

6/PRTS

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~~DOCOSAHEXAENOIC~~
USE OF DOCOSAHEXAENOIC ACID AND ARACHIDONIC ACID ENHANCING THE GROWTH OF PRETERM INFANTS

Field of Invention

The present invention concerns enhancing the growth of preterm infants involving administration of infant formula containing a combination of docosahexaenoic and arachidonic acid.

Background of the Invention

The long chain polyunsaturated fatty acids (LC PUFA) have been shown to be important in infant development. Particularly, arachidonic acid (ARA) and docosahexaenoic acid (DHA) are LC PUFA that are of special interest in infant nutrition because they are found in high concentrations in the brain (Sastry PS, Lipids of nervous tissue: composition and metabolism. Progress Lipid Res 1985;24:69-176) and the retina (Fliesler SJ and Anderson RE. Chemistry and metabolism of lipids in the vertebrate retina. Progress Lipid Res 1983;22:79-131). ARA (20:4n-6) and DHA (22:6n-3) are derived from the parent essential fatty acids linoleic acid (18:2n-6) and α -linolenic acid (18:3n-3) through alternate desaturation and elongation and accumulate rapidly in fetal neural tissue during the last months of gestation and the first months of postnatal life (Makrides M, Neuman MA, Byard RW, Simmer K, Gibson RA. Fatty composition of the brain, retina and erythrocytes in breast- and formula-fed infants. Am J Clin Nutr 1994;60:189-94).

- 2 -

Unlike term infants, preterm infants do not fully benefit from the maternal and placental LC PUFA supply during the last trimester of pregnancy. Even though preterm infants are capable of synthesizing both DHA and ARA from their 18 carbon precursors (Carnielli VP, Wattimena DJL, Luijendijk IHT, Boerlage A, Degenhart HJ, Sauer PJJ. The very low birth weight premature infant is capable of synthesizing arachidonic and docosahexaenoic acids from linoleic and linolenic acids. Pediat Res 1996;40:169-174), it remains unclear whether the rate of synthesis is adequate to meet the optimal needs for central nervous system accretion in the absence of a dietary supply of these fatty acids. Preterm infants are dependent on their own dietary supply of linoleic and α -linolenic acids through either human milk, which also contains small but significant amounts of ARA and DHA or through commercially available artificial formulas, none of which in the United States contain ARA and DHA.

It has been demonstrated in recent studies (Hoffman DR and Uauy R. Essentiality of dietary ω -3 fatty acids for premature infants: Plasma and red blood cell fatty acid composition. Lipids 1992;27:886-95) that the fatty acid composition of red blood cell membrane lipids in infants receiving formulas supplemented with DHA (0.35% of total fatty acids) was similar to human milk-fed infants. In the same study, Birch (Birch DG, Birch EE, Hoffman DR, Uauy RD. Retinal development in very-low-birth-weight infants fed diets differing in Omega-3 fatty acids. Investigation Ophthalmology Visual Science 1992;33:2365-76) found that retinal function improved with the provision of a dietary supply of DHA in very low birth weight infants.

- 3 -

The first year growth of preterm infants fed standard formula compared to marine oil LC PUFA supplemented formula was studied by Carlson et al. (Carlson SE, Cooke, RJ, Werkman SH, Tolley EA. First year growth of preterm infants fed standard compared to marine oil n-3 supplemented formula. *Lipids* 1992;27:901-907). The experimental formulas provided 0.2% of total fatty acids as DHA and also provided 0.3% as EPA (20:5n-3). This EPA concentration is higher than found in human milk while the DHA level is similar to human milk. Beginning at 40 weeks from conception, marine oil supplemented infants compared to controls had significantly lower weight, length, and head circumference. From this study, Carlson (Carlson SE, Werkman SH, Peeles JM, Cooke RJ, Tolley EA. Arachidonic acid status correlates with first year growth in preterm infants. *Proc Natl Acad Sci USA* 1993;90:1073-77) hypothesized that dietary ARA could improve first year growth of preterm infants, in the context of restoring growth to the level of control formula containing no LC PUFA.

In another study (Montalito, FB, et al., *Pediatric Research*, Vol 39, page 316A, abstract no. 1878) it was shown that male infants fed marine oil supplemented formula (containing DHA but essentially no ARA) had, by 4 to 6 months, lower head circumference, length, weight and fat free mass than standard formula fed infants. A third study also showed decreased weight at 9 and 12 months corrected age in preterm infants fed marine oil supplemented formula (with LC PUFA) to 2 months corrected age compared with control formula containing no LC PUFA (Carlson SE, et al., *Am. J. Clin. Nutr.*, 63 pp 687-97, 1996).

- 4 -

The prior art has demonstrated that infants with altered tissue LC PUFA levels, resulting from a lack of LC PUFA in their diets, may be at risk for neurological problems, may also have reduced scores on cognitive tests, and may have lower retinal development than human milk-fed infants. Worldwide regulatory organizations such as the WHO/FAO Expert Committee on Fats and Oils in Human Nutrition have recommended that LC PUFA be included in preterm infant formula. These recommendations have been made despite the negative effects observed of DHA supplements on growth. There has been no demonstration in the literature that ARA and DHA, particularly when added to infant formula, enhances the growth of infants above that demonstrated by control formulas not containing ARA and DHA.

Summary of the Invention

It has unexpectedly been discovered that preterm infants receiving infant formula supplemented with both DHA and ARA demonstrate enhanced growth. The present invention is directed to enhancing the growth of preterm infants comprising administering to said infants a growth enhancing amount of DHA and ARA.

Detailed Description of the Invention

As reported in a review of preterm infant growth by Carlson, SE, (The Jnl of Pediatrics, vol 125, pp 533-8, 1994) "After adjusting for postconceptional age, preterm infants show a decline (rather

- 5 -

than a catch-up) in the normalized weight from approximately 2 to 4 months past expected term."

Several prior art studies have documented the value of administering DHA to infants. However, when DHA, either as the primary LC PUFA or combined with EPA, is administered to preterm infants, said infants suffer from decreased growth. It has been suggested that ARA may be beneficial to growth; however, heretofore the growth effects of administering both DHA and ARA to preterm infants have been unknown. It has been surprisingly discovered that administering the combination of ARA and DHA results in enhanced growth of infants relative to infants fed DHA alone. It has also been discovered that preterm infants administered an infant formula containing ARA and DHA exhibit enhanced growth relative to preterm infants fed control formula without DHA and ARA, such as those formulas currently used in modern nurseries. It has further been discovered that practice of the method of the invention results in growth of preterm infants catching up in an unexpected short time to a reference group of normal term breast fed infants.

The time to achieve growth similar or equivalent to normal term breast fed infants by practice of the method of the invention is less than 9 months corrected age; preferably less than 6 months corrected age, more preferably less than 4 months corrected age, even more preferably less than 2 months corrected age, and most preferably no greater than term corrected age.

The method of the invention requires a combination of DHA and ARA. The weight ratio weight of ARA:DHA can be about 1:2 to about 5:1, preferably about 1:1 to about 3:1, and more preferably

- 6 -

about 2:1.

In the method of the invention the combination of DHA and ARA is preferably administered as part of an infant formula. The infant formula for use in the present invention is preferably nutritionally complete and typically contains suitable types and amounts of lipid, carbohydrate, protein, vitamins and minerals. The amount of lipid or fat typically can vary from about 3 to about 7 g/100 kcal. The amount of protein typically can vary from about 1 to about 5 g/100 kcal. The amount of carbohydrate typically can vary from about 8 to about 12 g/100 kcal. Protein sources can be any used in the art, e.g., nonfat milk, whey protein, casein, soy protein, hydrolyzed protein, amino acids, and the like. Carbohydrate sources can be any used in the art, e.g., lactose, glucose, corn syrup solids, maltodextrins, sucrose, starch, rice syrup solids, and the like. Lipid sources can be any used in the art, e.g., vegetable oils such as palm oil, soybean oil, palmolein, coconut oil, medium chain triglyceride oil, high oleic sunflower oil, high oleic safflower oil, and the like. Conveniently, commercially available infant formula can be used. For example, Enfamil®, Enfamil® Premature Formula, Enfamil® with Iron, Lactofree®, Nutramigen®, Pregestimil®, ProSobee® (available from Mead Johnson & Company, Evansville, Indiana, U.S.A.), Similac®, Isomil®, Alimentum®, Neocare®, and Similac® Special Care (available from Ross Laboratories, Columbus, Ohio, U.S.A.), may be supplemented with suitable levels of ARA and DHA at the proper ratios and used in practice of the method of the invention.

The form of administration of the DHA and ARA in the method of the invention is not critical, as

- 7 -

long as a growth enhancing amount is administered. Most conveniently, the DHA and ARA are supplemented into infant formula which is then fed to the infants. Alternatively, the DHA and ARA can be administered as a supplement not integral to the formula feeding, for example, as oil drops, sachets, in combination with other nutrient supplements such as vitamins, and the like.

The growth enhancing amount of DHA is typically about 2.5 mg/kg of body weight/day to about 60 mg/kg of body weight/day, preferably about 6 mg/kg of body weight/day to about 40 mg/kg of body weight/day, more preferably about 12 mg/kg body weight/day to about 30 mg/kg body weight/day, and even more preferably about 18 mg/kg of body weight/day to about 24 mg/kg of body weight/day.

The growth enhancing amount of ARA is typically about 5 mg/kg of body weight/day to about 120 mg/kg of body weight/day, preferably about 12 mg/kg of body weight/day to about 80 mg/kg of body weight/day, more preferably about 24 mg/kg body weight/day to about 60 mg/kg body weight/day, and even more preferably about 36 mg/kg of body weight/day to about 48 mg/kg body weight/day.

The amount of DHA in infant formulas for use in the present invention typically varies from about 2 mg/100 kilocalories (kcal) to about 50 mg/100 kcal, preferably about 5 mg/100 kcal to about 33 mg/100 kcal, more preferably about 10 mg/100 kcal to about 25 mg/100 kcal, and even more preferably about 15 mg/100 kcal to about 20 mg/100 kcal.

- 8 -

The amount of ARA in infant formula for use in the present invention typically varies from about 4 mg/100 kcal to about 100 mg/100 kcal, preferably about 10 mg/100 kcal to about 67 mg/100 kcal, more preferably about 20 mg/100 kcal to about 50 mg/100 kcal, and even more preferably about 30 mg/100 kcal to about 40 mg/100 kcal.

The infant formula supplemented with oils containing DHA and ARA for use in the present invention can be made using standard techniques known in the art. For example, replacing an equivalent amount of an oil normally present, e.g., high oleic sunflower oil.

The source of the ARA and DHA can be any source known in the art such as fish oil, single cell oil, egg yolk lipid, brain lipid, and the like. The DHA and ARA can be in natural form, provided that the remainder of the LC PUFA source does not result in any substantial deleterious effect on the infant. Alternatively, the DHA and ARA can be used in refined form. It is preferred that the LC PUFA used in the invention contain little or no EPA. For example, it is preferred that the infant formulas used herein contain less than about 20 mg/100 kcal EPA; preferably less than about 10 mg/kcal EPA; more preferably less than about 5 mg/100 kcal EPA; and most preferably substantially no EPA.

Preferred sources of DHA and ARA are single cell oils as taught in U.S. patent nos. 5,374,657, 5,550,156, and 5,397,591, the disclosures of which are incorporated herein by reference in their entirety.

The following examples are to illustrate the invention but should not be interpreted as a limitation thereon.

- 9 -

EXAMPLES

I CLINICAL STUDY DESIGN

1. INTRODUCTION

This study is a double-blind, randomized, controlled parallel design, prospective trial of premature infant formulas containing microalgae and fungi-derived oils which contain a part of their constituents arachidonic acid and docosohexaenoic acid. Formula feeding subjects will be randomized into one of 3 feeding groups:

- premature formula plus DHA (about 0.13% of energy) and ARA (about 0.26% of energy)
- premature formula plus DHA (about 0.13% of energy)
- premature formula WITHOUT DHA and ARA

The products have the same nutrient composition (see Appendix A) and differ only in the level of DHA and ARA. The products will be blinded. The present order of formula has no relationship to randomization.

Normal, term, breast fed infants will be enrolled to provide a normal visual acuity reference.

Fifty evaluable subjects will be completed in each group. Premature infants will remain on study formulas after reaching 90 kcal/kg/d for a minimum of 28 days or until hospital discharge whichever is longer. After 28 days or discharge, whichever is longer, all premature infants will receive Enfamil or Enfalac with Iron. If medically indicated, ProSobee, Lactofree, Alactamil, Nutramigen, or Pregestimil may be used in place of Enfamil or Enfalac with Iron. Term infants will receive at least 85% of their nutrition from breast milk. Primary measures of effectiveness will include visual acuity and red blood cell membrane fatty acid profiles (i.e. DHA and ARA levels). The measure of safety will be growth and adverse experience reports.

2. SUBJECTS

2.1 SOURCE AND CHARACTERIZATION OF STUDY GROUP

Acceptable preterm subjects will be relatively healthy premature infants taking

- 10 -

preterm formula. Anticipated hospitalization should be sufficient to allow for 28 days of enteral intake \geq 90 kcal/kg/d and \geq 85% study formula intake. All races and both sexes will be eligible for the study.

2.2 INCLUSION CRITERIA

Preterm infants

- Birth weight \geq 900 g
- Formula feeding at time of study enrollment
- Anticipate enteral intake of \geq 90 kcal/kg/day for \geq 28 days before discharge home
- Informed consent obtained

Term Infants:

- 38 to 42 weeks gestation
- Committed to breast feeding
- Informed Consent obtained

2.3 EXCLUSION CRITERIA

Preterm infants

- \geq 1500 g at birth

Preterm and Term Infants:

- History of underlying disease or congenital malformation which in the opinion of the investigator is likely to interfere with the evaluation of the subject
- More than 24 days between birth and full oral feeds (\geq 90 kcal/kg/d)
- Small (<10th percentile) for gestational age at birth (SGA)
- Necrotizing enterocolitis as diagnosed by the physician

- 11 -

Other gastrointestinal disease

Impaired visual or ocular status at birth

2.4 CONCOMITANT MEDICATIONS, HOSPITALIZATIONS, ILLNESSES

No medication which may effect FPL response may be used within 3 days of measurement.

No evidence of viral or bacterial infection during FPL testing.

No medications known to effect lipid metabolism (e.g., heparin at therapeutic levels)

3. STUDY PRODUCT INFORMATION

3.1 FORMULATIONS

Nutrient composition is included as Appendix A.

4. STUDY PROCEDURES

4.2.1 ENROLLMENT

Enrollment will take place over a 6 month period. Ideally, sufficient subjects will be enrolled so that 10 subjects in each group complete the study at each site for the multi-center trial. A total of 50 infants per formula group will complete this trial.

4.2.2 SCHEDULE OF EVENTS (SEE FLOW CHART, SECTION 8.4)

4.2.2.1 RECRUITMENT

Mothers of eligible, healthy, preterm formula fed infants and term, breastfed infants will be contacted, the study explained to them, and if they are agreeable, written informed consent obtained.

Term infants may be enrolled anytime from birth until or during the 48 week visit.

- 12 -

4.2.2.2 RANDOMIZATION

Recruited formula fed subjects will be randomized into study groups. Randomization can occur anytime after enteral feeds reach 50 kcal/kg/day until commencement of full enteral feeds (i.e., ≥ 90 kcal/kg/day).

4.2.2.3 FEEDING

All premature infants will receive their assigned study formula after informed consent has been granted and enteral feeds are at least 50 kcal/kg/day. The infant will remain on study formula 28 days after reaching 90 kcal/kg/d or until hospital discharge, whichever is longer. Oral feeding amount, strength and rate will advance as appropriate for the clinical management of the infant.

All parents will be instructed not to feed solid foods during the study. The parents will be instructed that the study formula or breast milk is to serve as the sole source of food from enrollment to study end.

4.2.2.4 BASELINE DATA COLLECTION

The following data will be collected by the Investigator at the time of enrollment and randomization on the case report forms:

- Informed consent of parent obtained.
- Post conceptual age.
- That the subject is a premature infant, with Birth weight ≥ 900 gm and ≥ 1500 gm or a normal term infant between 38 and 42 weeks gestational age.
- That the preterm subject is receiving infant formula or term infant is committed to breast feeding.
- Anticipated preterm infant enteral intake of ≥ 90 kcal/kg/day for ≥ 28 days prior to discharge home.
- That the subject has no history of underlying disease, inborn error of metabolism, or congenital malformation which in the opinion of the Investigator is likely to interfere with the evaluation of the study formulas.

- 13 -

That the subject is not small (<10th percentile) for gestational age at birth.

That the subject does not have necrotizing enterocolitis as diagnosed by a physician.

That the subject does not have a gastrointestinal disease.

No more than 24 days between birth and full enteral feeds (i.e., ≥ 90 kcal/kg/day).

That the subject did not have impaired visual or ocular status at birth.

Birth date, sex, race.

Birth weight, length and head circumference

4.2.2.5 INVESTIGATOR PERIODIC DATA COLLECTION

"During hospitalization, preterm subjects will have their weight recorded daily while they are receiving study formula. Length and head circumference will be recorded weekly, along with an additional weight measurement. For a given subject, the same scale should be used for the weekly weight measurement."

"Weight, length, and head circumference will also be recorded at the 40, 48, and 57 week post conceptual age visit (preterm) and 56 and 119 days of age visit (term)."

4.2.2.6 BLOOD DRAW

When preterm infant enrolls in the study and again at termination of study formula (i.e., hospital discharge or 28 days after reaching 90 kcal/kg/d of study product), the Investigator will ascertain that the infant is essentially solely formula fed. If this criteria is met, 1.2 ml/blood will be drawn for blood lipids. The sample will be processed as described in Appendix B.

An attempt will also be made to draw a similar blood sample at the 48 weeks PCA visit when visual acuity is measured in both term and preterm infants.

- 14 -

4.2.2.7 VISUAL ACUITY BY FORCED CHOICE PREFERENTIAL LOOKING (FPL) AT 48 AND 57 WEEKS \pm 4 DAYS POST-CONCEPTUAL AGE

When the infant is 48 and 57 weeks \pm 4 days post-conceptual age, trained persons at each study site will follow the Teller Acuity Card Procedure for the measurement of visual acuity of all study subjects. It is essential that only persons who are trained in the FPL procedure for determining visual acuity do the testing. If necessary, training of responsible persons and documentation of completion of successful training will be done at Children's Hospital Medical Center Ophthalmology Department in Seattle, Washington, according to the procedure attached as Appendix C.

If the infant cannot complete the procedure at 48 or 57 weeks \pm 4 days postconceptual age (i.e., too fussy, too sleepy, too inattentive) the test should be repeated within 7 days.

4.2.2.8 INTERIM EVALUATION

At preterm infant hospital discharge or 28 days after reaching 90 kcal/kg/d of study formula feeding, whichever is longer, the investigator will fill out an "Interim Evaluation" form. After reviewing the subject's records and discussion with the parents and staff, the investigator will indicate whether:

- Whether or not the subject completed at least 28 days of study formula intake \geq 90 kcal/kg/d and both blood samples obtained
- If the study was not completed, and reason
- Whether or not the subject received steroids (glucocorticoids)
- Investigator's evaluation of the study formula

The first and last dates study material was taken will be recorded.

4.2.2.9 FINAL EVALUATION

At the final study visit (57 weeks postconceptual age) or earlier if the subject drops out, the Investigator will fill out a "Final Evaluation" Case Report Form. After reviewing the subject's records and discussion with the parents, the Investigator will indicate whether the subject:

- 15 -

- (1) Completed feeding regimen and all study parameters (i.e., anthropometrics and visual acuity measured).
- (2) Did not complete feeding regimen.
- (3) Not completed and reason.

4.3 CLINICAL OBSERVATIONS

4.3.1 PHYSICAL EXAMINATIONS

Subjects will have weight, length and head circumferences recorded at birth, weekly while hospitalized, then at 40, 48, and 57 weeks \pm 4 days postconceptual age.

Body weight will be measured using an electronic balance or a double beam balance accurate to 10 g or $\frac{1}{2}$ oz with non-detachable weights. During hospitalization, if more than one such balance is employed in the practice, either one balance should be designated the study balance and all study weights will be carried out on that balance for a particular subject, or the balances will be checked and certified to register the same weight throughout the range of weights expected. Outpatient weights will be obtained on a calibrated office scale.

Documentation indicating balance calibration of the outpatient balance carried out within 12 months of study initiation will be supplied to the Sponsor.

Length will be measured with the infant in recumbent position with the help of two examiners and a suitable measuring apparatus. One person holds the subject's head in contact with a fixed vertical headboard and a second person holds the subject's feet, toes pointing directly upward and, also applying gentle traction. The baby is measured from the headboard to the soles of the feet with a non-stretching tape measure.

Head circumference will be measured, employing a flexible, non-stretchable cloth or vinyl tape.

- 16 -

4.3.2 VISUAL ACUITY BY FORCED CHOICE PREFERENTIAL LOOKING (FPL)

Visual acuity will be determined at 48 and 57 weeks \pm 4 days postconceptual age according to procedures outlined in Appendix C.

4.3.3 LABORATORY TESTS

Blood will be drawn from preterm infants by heel prick or venipuncture when study formula is begun and terminated. An attempt will be made to draw blood at 48 weeks \pm 4 days PCA from both term and preterm infants. Procedures for handling the blood are described in Appendix B.

- 17 -

4.4 Flow Chart

EVENT	PRETERM				TERM			
	Birth	Enteral Intake > 50 kcal/kg/d	Termination of Study Formula †	Visit 1 40 wks ± 4d PCA	Visit 2 40 wks ± 4d PCA	Visit 3 57 wks ± 4d PCA	Visit 1 40 wks ± 4d PCA	Visit 2 40 wks ± 4d PCA
Randomization	✓							
Study Formula	✓							
Enfamil w/Iron		✓		✓	✓			
Human Milk						✓	✓	✓
Physical								
Weight	✓	✓*	✓	✓	✓	✓	✓	✓
Length	✓	✓*	✓	✓	✓	✓	✓	✓
Head Circumference	✓	✓*	✓	✓	✓	✓	✓	✓
Blood Draw		✓	✓		✓		✓	
Visual Acuity Test					✓	✓	✓	✓
Illnesses					✓	✓	✓	✓
Interim Assessment				✓				
Final Assessment								

(when the subject discontinues or completes)

✓ Medical problems related to or affecting formula consumption will be recorded when they occur.
 * Recorded daily and weekly during hospitalization.

† At hospital discharge or 28 days of study formula intake (after reaching 90 kcal/kg/d), whichever is later.

- 18 -

5. CRITERIA FOR RESPONSE

Criteria for response will depend upon the following:

- Visual Acuity better than the control formula.
- Visual Acuity comparable to breastfed term infant.
- Red Blood Cell phosphatidyl ethanolamine DHA and ARA weight % greater than formula control group.
- Growth as measured by weight achieved at 48 and 57 weeks postconceptual age comparable to formula control group.

6. STATISTICS

6.1 RANDOMIZATION

If the subject meets the inclusion and exclusion criteria, randomization to one of three formula groups will take place. The randomization schedule will be provided by Mead Johnson Research Center. A separate randomization schedule will be provided for males and females.

6.2 SAMPLE SIZE

The primary parameter of interest is visual acuity as measured by the Forced Choice Preferential Looking (FPL). The minimal clinically relevant difference was determined to be 0.5 octave. A consultant in the field of visual acuity estimated the standard deviation to be 0.5 octave. This value was increased to .7 octave in case more variability was experienced in this study. Thirty-two subjects per group are needed to attain 80% power when testing at an alpha level of 0.05.

A sample size estimate of 50 per group was determined to achieve $\alpha + 0.05$, $\beta + 0.20$, for weight of infants receiving study oil being greater than 400 gm below control at 48 weeks postconceptual age or 500 g below control at 57 weeks postconceptual age with a standard deviation of 800 g. It was therefore determined that 50 subjects per group will be used in the study.

- 19 -

6.3 ANALYTICAL PLAN

Visual acuity data will be recorded in cycles per cm. These values will be converted to cycles per degree using the following formula:

$$\text{cycles/degree} = \frac{38 \times \text{cycles/cm}}{55}$$

A log transformation will be applied to the data prior to analysis. Analysis of variance techniques will be used to assess feeding regimen group differences in visual acuity. If the overall F test for feeding regimen is significant at al alpha level of 0.05, pairwise comparisons will be made at an alpha level of 0.05. If no significant differences are detected, then a post-study power analysis will be performed to demonstrate that the study had adequate power to detect the minimal clinically relevant difference.

Analysis of variance will be used to assess feeding regimen differences in phosphatidyl choline DHA and ARA levels and in phosphatidyl ethanolamine DHA and ARA levels at each time point. If the overall F test is significant at al alpha level of 0.05, then pairwise comparisons will be made at an alpha level of 0.05.

Analysis of variance will be used to assess feeding regimen differences in weight at 48 and 57 weeks postconceptual age. The statistical model will include terms for feeding regimen, study center, sex and all two-way interactions. Non-significant interactions will be removed from the final statistical model. Two one-sided tests will be performed comparing each experimental formula (EC) with the control formula (CF). The hypothesis to be tested is as follows:

$$H_0 = \text{Weight (CF)} \leq \text{Weight (EF)}.$$

The alternative hypothesis is as follows:

$$H_1 = \text{Weight (CF)} > \text{Weight (EF)}.$$

If H_0 if rejected and the mean weight of the control formula exceeds that of the experimental formula by more than 400 mg at 48 weeks postconceptual age or by 500 g at 57 weeks postconceptual age then the conclusion is that the experimental formula does not exceed that of the experimental formula by more than 400 g at 48 weeks postconceptual age

- 20 -

or by 500 mg at 57 weeks postconceptual age then the conclusion is that the experimental formula does provide adequate growth. If H_0 is not rejected then a post-study power analysis will be performed to demonstrate that the study had adequate power to detect the above mentioned clinically relevant differences. If adequate power is achieved then the conclusion is that the experimental formula does provide adequate growth.

Fisher's exact test will be used to compare the proportion of subjects in each group with illness/symptoms of concern during the study. The analysis will be performed for each type of illness/symptom reported, with classification of investigator terms into similar terminology made as necessary.

- 21 -

APPENDIX A NUTRIENT COMPOSITION OF FORMULAS

All study formulas are 24 kcal/fl oz and are identical in composition to marketed Enfamil Premature Formula except for the study oils employed. These oils are described in the protocol.

NUTRIENT	STUDY FORMULAS AMOUNT/100 kcal	ENFAMIL WITH Fe
Protein, g	3	2.2
Fat, g	5.1	5.6
Carbohydrate, g	11.1	10.3
Vitamin A IU	1250	310
Vitamin D IU	270	63
Vitamin E IU	6.3	.2
Vitamin K mcg	8	8
Thiamine, mcg	200	78
Riboflavin, mcg	300	150
Vitamin B ₆ , mcg	150	63
Vitamin B ₁₂ , mcg	0.25	0.23
Niacin, mcg	4000	1250
Folic Acid, mcg	35	15.6
Pantothenate, mcg	1200	470
Biotin, mcg	4	2.3
Vitamin C, mg	20	8.1
Choline, mg	12	15.6
Inositol, mg	17	4.7
Calcium, mg	165	78
Phosphorus, mg	83	53
Magnesium, mg	6.3	7.8
Iron, mg	1.8	0.5
Zinc, mg	1.5	0.78
Manganese, mcg	6.3	15.6
Copper, mcg	125	94
Iodine, mcg	25	6
Sodium mg (mEq)	39 (1.7)	27(1.17)
Potassium mg (Meq)	103 (2.6)	108 (2.8)
Chloride mg (Meq)	85 (2.4)	63 (1.77)

- 22 -

II

FINAL STUDY REPORT

Study Design: This double-blind, parallel-group study (project 3338) was carried out in 16 neonatal centers (study numbers 9698-9709, 9712, 9723, 9743, and 9746) in North America. Three premature infant feedings were compared. Each had the same composition except for the incorporation of fungal and/or micro algal oils up to about 3% of the fat blend to provide the experimental levels of docosahexaenoic acid (DHA) and arachidonic acid (ARA). The control formula (C, Enfamil® Premature Formula) contained no DHA or ARA, the DHA formula (D) contained about 0.15% of energy as DHA (0.34% of fat), and the DHA+ARA formula (DA) contained about 0.14% of energy as DHA (0.33% of fat) and 0.27% of energy as ARA (0.60% of fat). The formulas were fed to 284 randomized infants weighing 846 to 1560 grams at birth for at least 28 days. Upon completion of study formula intake, they were given routine infant formula and followed through 4 months gestationally corrected age. A group of 90 exclusively human milk fed term infants were enrolled and followed to 4 months of age as a reference group (H).

Study Objective and Statistical Analysis: The primary objective of this study was to establish the safety of feeding D or DA to preterm infants during their initial hospitalization as measured 1) by growth, acceptance and tolerance while consuming the formula for at least 1 month and 2) by close monitoring and observation for a 4 to 5 month follow-up period (4-5 times the treatment period) while consuming unsupplemented routine term infant formula. The primary growth parameter selected was weight with evaluation of the proposition that weight on test formula was greater than or equal to weight on control formula. The one sided statistical test for an adverse effect on growth maximized the power to detect a difference should one be present. A two-sided test was used for all other parameters. A p-value of less than 0.05 was used to establish significance.

Secondary objectives of the study were 1) to evaluate the impact of fatty acid levels in erythrocyte phospholipids at the end of study feeding and 2) to determine if any effect on mean visual acuity greater than half an octave could be demonstrated at 2 and 4 months corrected age.

Results: Six infants were just outside the weight parameters and five infants just older than the less than 24 days chronological age parameter for enrollment in the study. In each case, judgement by the clinical or medical monitor was made to include them in the study prior to enrollment based on their homogeneity with other study infants in all other particulars, e.g., state of health, type of medical complications, and weight for gestational age. All these infants were included in the analysis of the study results.

The formula groups were comparable at enrollment (See table 1). Post-conceptual age, weight, length, and head circumference at enrollment did not differ among the groups.

All groups experienced comparable final study status (See table 2). Drop outs did not differ among the formula fed groups during hospitalization. There also were no differences in drop outs among the four groups at study completion.

- 23 -

Both formulas D and DA provide adequate growth when compared to formula C (See table 3, figure 1, and Appendix 1). Weight gain during hospitalization was no less on D or DA than on C, 33.3, 34.7, and 30.7 g/day, respectively. Furthermore, no less weight was achieved on D or DA than on C at 40, 48, and 57 weeks post-conceptual age (See table 4, figure 2, and Appendix 1); statistical power was greater than 0.89 to detect a clinically relevant decrease.

Post-hoc analysis reveals that infants on DA grew faster than infants receiving C and D (See table 5 and figure 1). This enhanced growth provided faster "premature infant catch-up" compared to C and D. Weight achieved by the DA group (3198 g) was higher than C (3075 g) and D (3051 g) at 40 weeks post-conceptual age but had not fully caught up to the term birth weight (3438 g) of group H (See table 4 and figure 2). This catch up trend continued through 48 to 57 weeks by which time the mean weight of group DA did not differ from group H while groups C and D remained significantly lower.

Length was not different among the formula groups either during hospitalization or the follow-up period, although the ordered sequence of mean lengths was the same as for the weights (See table 7 and figure 3). This is likely at least partially due to length being a less sensitive parameter of growth than weight. For the same reason, the mean lengths of group H infants were higher than that of all the premature infant groups at 40, 48 and 57 weeks post-conceptual age indicating slower catch up in this parameter.

Head circumference is the least sensitive parameter of growth and was not different among any of the four groups at any time measured except at 40 weeks postconceptual age (See table 8 and figure 4). At this time, as expected, the birth head circumference of group H was smaller than the formula fed premature infants possibly due to molding of labor and to insufficient time for adjustment to the extrauterine environment.

Visual acuity has reportedly been enhanced in studies where DHA supplemented formulas were fed to premature infants both in the hospital and continuing after discharge. In this study, visual acuity was measured about 3 months and then about 5 months after stopping study formula to determine whether a residual beneficial effect of at least half an octave might be observed.

Although no difference in visual acuity was found among the formula groups at these times (See table 8 and figure 5), the acuity card method used, the length of study formula feeding, and/or the length of time not on study formula at the time of measurement may have precluded its detection. However, at 57 weeks post-conceptual age, the breast fed term infant group did have statistically higher visual acuity scores than the test formula groups. But even these differences were at most only 0.33 octave and were clinically insignificant (See figure 6). It is important to note that the breast fed infants continued to receive DHA and ARA during the 3-5 month follow-up period while the formula fed groups did not. Thus, this minor difference in performance was not unexpected based on previous study findings and on developmental differences between term and preterm infants even at the same gestational age.

Individual fatty acid levels were determined in the phosphatidylcholine and phosphatidylethanolamine fractions of red blood cells before formula feeding, at the conclusion of test formula feeding, and at 48 weeks post-conceptual age (See tables 9 and 10). The premature infant groups were comparable at the beginning of test formula feeding. At the conclusion of test

formula feeding, individual fatty acid levels varied among the groups. DHA and ARA were statistically significantly higher in the respectively supplemented groups. Other fatty acid levels reflected the impact of the supplementation. No clinically significant alterations in fatty acid levels or metabolism were identified. After discontinuing study formula and consuming a diet without DHA or ARA for about 3 months, no differences in fatty acid levels among formula fed groups were detectable, except for phosphatidylethanolamine levels of 18:2 (range 8.9-9.3%) and DHA (range 3.2-4.1%) which differences were not identified as being clinically significant. However, the breast fed group shows statistically significant differences in 13 fatty acid levels compared to the formula fed infants. These differences are undoubtedly due to the differences in fatty acid composition of human milk and the term formulas including the lack of DHA and ARA in the latter.

Preterm infant complications were similar in all groups (See table 11). Over 80% of all infants were ophthalmologically examined and over 90% had ultrasound evaluation of their heads. Specifically, the incidence and severity of retinopathy of prematurity (ROP or retrolental fibroplasiaRLF) and the incidence of intraventricular hemorrhage or its complications did not differ among formula groups. No feeding group related complications were identified.

Serious adverse experiences did not differ ($p=0.93$) among the formula groups and were in the range of those expected in a premature infant population while on study formula: 6% in group C, 5% in group D, and 6% in group DA (See table 12). After the experimental formula phase, serious adverse experiences still did not differ among the preterm groups (See table 13): 13% in group C, 15% in group D, and 15% in group DA. However, the term infant breast fed group had significantly fewer serious adverse experiences (1%, $p=0.002$) as expected. Two infants reportedly suffered sudden infant death syndrome (SIDS), one in group C and one in group D; there was no significant difference in this complication among all four groups.

Conclusions: We conclude that feeding 0.13% of calories as DHA from micro algal oil and feeding 0.13 % of calories as DHA from micro algal oil plus 0.26% of calories as ARA from fungal oil in the matrix of premature infant formula to premature infants during the period of their initial hospitalization prior to 40 weeks post conceptual age is safe. These micro algal and fungal oil supplements do not result in any adverse effect on growth, clinical complications, or untoward events. Furthermore, this study reveals that growth benefits accrue to premature infants fed Enfamil Premature Formula supplemented with DHA and ARA from these sources compared to unplemented formula or formula supplemented with only DHA. No measurable benefit on visual acuity was identified when infants were tested at about 3 and 5 months after the supplemented formula was discontinued (2 and 4 months corrected age). However, providing human milk levels of intake of long chain polyunsaturated acids are warranted because they are critical to brain development and foster enhanced catch-up growth during this early development period.

-25-

Table 1
Birth Statistics of Premature Subjects

	n	Mean (std)	Range	p-value
Post-Conceptual Age (Weeks)				
Control	62	29.5 (1.7)	25 - 33	
DHA	66	30.0 (1.4)	26 - 32	0.076
DHA+ARA	66	29.7 (1.7)	26 - 34	
Birth Weight (g)				
Control	62	1233.1 (176.6)	846 - 1560	
DHA	66	1272.8 (168.1)	900 - 1545	0.25
DHA+ARA	66	1278.9 (177.6)	910 - 1535	
Birth Length (cm)				
Control	60	38.4 (2.3)	34 - 43.75	
DHA	66	38.6 (2.2)	33 - 43.5	0.62
DHA+ARA	66	38.7 (2.3)	33 - 44	
Birth Head Circumference (cm)				
Control	61	26.9 (1.5)	23.5 - 30.5	
DHA	64	27.3 (2.1)	22 - 37	0.53
DHA+ARA	65	27.2 (1.6)	23.5 - 30	

-26-

Table 2
Summary of Final Study Status

	Regimen				p-value
	Control	DHA	DHA+ARA	HM	
Immediate dropout, study formula never consumed		2	2		
Study Formula Phase *					
Completed	52 (84%)	59 (89%)	62 (94%)		0.20
Discontinued	10 (16%)	7 (11%)	4 (6%)		
Reason discontinued					
>96 cumulative hours NPO	3	1			
<28 days of intake \geq 90 kcal/kg/day	3	3			
Complications unrelated to study formula	1				
NEC or other GI disease		1	1		
Formula intolerance			1		
Parents request	2	2	1		
Not off oxygen prior to discharge			1		
Protocol violation	1				
Term Formula Phase **					
Completed	45 (87%)	47 (80%)	53 (85%)	77 (86%)	0.74
Discontinued	7 (13%)	12 (20%)	9 (15%)	13 (14%)	

*The CRFs for 9709-003 (DHA) and 9743-304 (DHA) were marked discontinued because the subjects met the study formula intake criteria for only 27 days. These subjects are counted completed here because subjects at other sites with similar intakes were marked completed.

**Based on subjects who completed the Study Formula phase. During the Term Formula phase, subjects were fed marketed formula. Switching to a different marketed formula did not result in termination from the Term Formula phase.

-27-

Table 3
Weight Growth Rate During Study Formula Phase

Regimen	n	Least Square Mean	Standard Error	Comparison		Study p-value*	Gender p-value	Gender-by-Regimen p-value
				Comparison	p-value*			
Control	60	30.7	1.1	Control vs DHA	0.967	0.00	0.17	0.87
DHA	65	33.3	1.1	Control vs DHA+ARA	0.998			
DHA+ARA	66	34.7	1.1					

* One-sided test of the null hypothesis: Test Mean \geq Control Mean

-28-

Table 4
Weight at 40, 48, and 57 Weeks Post-Conceptual Age

Weeks Post-Conceptual Age	Regimen	n	Least Square Mean	Standard Error	Comparison	Comparison p-value*	Study p-value	Gender p-value	Gender by Regimen p-value
40	Control	52	3075.3	67.9	Control vs DHA	0.388	0.59	0.45	1.00
	DHA	54	3051.4	66.8	Control vs DHA+ARA	0.931			
	DHA+ARA	59	3198.2	62.9	HM vs DHA	0.000			
	HM	90	3437.7	60.6	HM vs DHA+ARA	0.001			
48	Control	53	4711.0	96.6	Control vs DHA	0.160	0.58	0.13	0.29
	DHA	51	4663.8	97.3	Control vs DHA+ARA	0.995			
	DHA+ARA	57	5039.1	91.0	HM vs DHA	0.000			
	HM	81	5181.5	85.9	HM vs DHA+ARA	0.114			
57	Control	47	6045.4	139.5	Control vs DHA	0.371	0.58	0.29	0.33
	DHA	49	5987.2	137.6	Control vs DHA+ARA	0.940			
	DHA+ARA	55	6312.9	127.9	HM vs DHA	0.005			
	HM	76	6405.0	126.7	HM vs DHA+ARA	0.278			
					HM vs Control	0.014			

* One-sided test of the null hypothesis: Test Mean \geq Control Mean

-29-

Table 5
Post-hoc Analysis of Weight

Time	Comparison	Two-sided p-value
Weight Gain During Study Formula Phase	C vs. DHA C vs. DHA+ARA DHA vs. DHA+ARA	0.067 0.004 0.30
Weight at 40 Weeks pca	C vs. DHA C vs. DHA+ARA DHA vs. DHA+ARA HM vs. DHA HM vs. DHA+ARA HM vs. C	0.78 0.14 0.074 <0.001 0.002 <0.001
Weight at 48 Weeks pca	C vs. DHA C vs. DHA+ARA DHA vs. DHA+ARA HM vs. DHA HM vs. DHA+ARA HM vs. C	0.72 0.011 0.004 <0.001 0.23 <0.001
Weight at 57 Weeks pca	C vs. DHA C vs. DHA+ARA DHA vs. DHA+ARA HM vs. DHA HM vs. DHA+ARA HM vs. C	0.74 0.12 0.057 0.010 0.56 0.028

Table 6
Length at 40, 48, and 57 Weeks Post-conceptual Age

Weeks Post-Conceptual Age	Regimen	n	Least Square Mean	Standard Error	Regimen p-value	Pairwise Comparison	Pairwise p-value	Study p-value	Gender p-value	Gender-by-Regimen p-value
40	Control	52	48.4	0.4	0.000	Control vs DHA	0.242	0.03	0.88	0.63
	DHA	54	47.8	0.4		Control vs DHA+ARA	0.233			
	DHA+ARA	58	49.0	0.4		HM vs DHA	0.000			
	HM	89	50.6	0.4		HM vs DHA+ARA	0.000			
48	Control	53	54.7	0.3	0.000	Control vs HM	0.000	0.00	0.14	0.52
	DHA	52	54.6	0.3		Control vs DHA+ARA	0.824			
	DHA+ARA	57	55.5	0.3		HM vs DHA	0.079			
	HM	81	57.4	0.3		HM vs DHA+ARA	0.000			
57	Control	47	60.7	0.4	0.000	Control vs HM	0.000	0.00	0.02	0.84
	DHA	49	60.5	0.4		Control vs DHA+ARA	0.615			
	DHA+ARA	54	61.3	0.3		HM vs DHA	0.236			
	HM	76	62.4	0.3		HM vs DHA+ARA	0.000			
						Control vs HM	0.006			
						DHA vs DHA+ARA	0.000			
							0.000			

-31-

Table 7 Head Circumference at 40, 48, and 57 Weeks Post-Conceptual Age

Weeks	Pre-Conceptual Age	Regimen	n	Least Square Mean	Standard Error	Regimen p-value	Pairwise Comparison	Pairwise p-value	Study p-value	Gender p-value	Gender-by-Regimen p-value					
							Control	DHA	DHA+ARA	HM	Control vs DHA	Control vs DHA+ARA	HM vs DHA	HM vs DHA+ARA	Control vs HM	DHA vs DHA+ARA
40	Control	Control	51	35.4	0.2	0.000	Control vs DHA	0.931	0.91	0.00	0.900	0.900	0.000	0.000	0.000	0.38
		DHA	53	35.4	0.2	0.000	Control vs DHA+ARA	0.931	0.91	0.00	0.900	0.900	0.000	0.000	0.000	0.38
		DHA+ARA	58	35.5	0.2	0.000	HM vs DHA	0.931	0.91	0.00	0.900	0.900	0.000	0.000	0.000	0.38
		HM	85	34.5	0.2	0.000	HM vs DHA+ARA	0.931	0.91	0.00	0.900	0.900	0.000	0.000	0.000	0.38
48	Control	Control	52	39.1	0.2	0.983	Control vs DHA	0.81	0.81	0.00	0.800	0.800	0.000	0.000	0.000	1.00
		DHA	51	39.0	0.2	0.983	Control vs DHA+ARA	0.81	0.81	0.00	0.800	0.800	0.000	0.000	0.000	1.00
		DHA+ARA	56	39.0	0.2	0.983	HM vs DHA	0.81	0.81	0.00	0.800	0.800	0.000	0.000	0.000	1.00
		HM	81	39.0	0.1	0.983	HM vs DHA+ARA	0.81	0.81	0.00	0.800	0.800	0.000	0.000	0.000	1.00
57	Control	Control	47	41.9	0.2	0.689	Control vs DHA	0.64	0.64	0.00	0.630	0.630	0.000	0.000	0.000	0.85
		DHA	49	41.6	0.2	0.689	Control vs DHA+ARA	0.64	0.64	0.00	0.630	0.630	0.000	0.000	0.000	0.85
		DHA+ARA	53	41.7	0.2	0.689	HM vs DHA	0.64	0.64	0.00	0.630	0.630	0.000	0.000	0.000	0.85
		HM	76	41.7	0.2	0.689	HM vs DHA+ARA	0.64	0.64	0.00	0.630	0.630	0.000	0.000	0.000	0.85

- 32 -

Table 8
Visual Acuity at 48 and 57 Weeks Post-Conceptual Age

Weeks Post-Conceptual Age	Regimen	n	Geometric mean	Least Square Mean	Standard Error	Regimen p-value	Pairwise p-value	Study p-value
			(cycles/deg)	(log base2 cycles/deg)	(octaves)	Comparison	Comparison	p-value
48	Control	51	1.72	0.78	0.10	0.950	0.000	0.000
	DHA	50	1.80	0.85	0.10			
	DHA+ARA	57	1.72	0.78	0.09			
	HM	81	1.75	0.81	0.09			
57	Control	46	3.47	1.79	0.08	0.004	0.697	0.000
	DHA	47	3.37	1.75	0.08		Control vs DHA	0.071
	DHA+ARA	55	3.06	1.61	0.07			
	HM	77	3.85	1.94	0.07		HM vs DHA+ARA	0.042
							HM vs DHA	0.000
							Control vs HM	0.113
							DHA vs DHA+ARA	0.158

Table 9
Red Blood Cell Phosphatidylcholine Fatty Acids

Time	Fatty Acid	Regimen	n	Arithmetic Mean	Standard Error	Median	Regimen p-value	Pairwise Comparison	Pairwise p-value
Study Form Initiation	12:0	Control	52	0.081	0.019	0.036	0.762	Control vs DHA+ARA	0.030
		DHA	58	0.066	0.013	0.030			
		DHA+ARA	61	0.057	0.009	0.031			
Study Form Initiation	14:0	Control	52	0.623	0.036	0.599	0.559	Control vs DHA+ARA	0.656
		DHA	58	0.663	0.031	0.686			
		DHA+ARA	61	0.661	0.031	0.656			
Study Form Initiation	14:1	Control	52	0.045	0.009	0.021	0.165	Control vs DHA+ARA	0.016
		DHA	58	0.026	0.005	0.016			
		DHA+ARA	61	0.035	0.006	0.018			
Study Form Initiation	16:0	Control	52	36.706	0.540	36.594	0.884	Control vs DHA+ARA	35.578
		DHA	58	36.363	0.462	36.377			
		DHA+ARA	61	36.877	0.445	35.987			
Study Form Initiation	16:1	Control	52	0.940	0.049	0.865	0.441	Control vs DHA+ARA	0.976
		DHA	58	0.981	0.050	0.964			
		DHA+ARA	61	1.094	0.064	0.931			
Study Form Initiation	18:0	Control	52	11.660	0.243	11.468	0.243	Control vs DHA+ARA	11.201
		DHA	58	11.402	0.238	11.219			
		DHA+ARA	61	11.016	0.192	11.174			
Study Form Initiation	18:1	Control	52	17.053	0.298	17.308	0.679	Control vs DHA+ARA	16.935
		DHA	58	17.219	0.391	16.988			
		DHA+ARA	61	17.256	0.271	16.988			
Study Form Initiation	18:2	Control	52	18.614	0.525	18.952	0.830	Control vs DHA+ARA	19.603
		DHA	58	18.631	0.505	18.824			
		DHA+ARA	61	18.573	0.466	18.824			
Study Form Initiation	18:3n6	Control	52	0.120	0.008	0.116	0.196	Control vs DHA+ARA	0.010
		DHA	58	0.136	0.008	0.130			
		DHA+ARA	61	0.150	0.009	0.134			

- 34 -

Table 9
Red Blood Cell Phosphatidylcholine Fatty Acids

		Fatty Acid	Regimen	n	Arithmetic Mean	Standard Error	Median	Regimen p-value	Pairwise Comparison	Pairwise p-value
Study Form Initiation	20:0	Control	52	0.399	0.050	0.224	0.236	0.647		
		DHA	58	0.337	0.035					
		DHA+ARA	61	0.310	0.037	0.188				
Study Form Initiation	18:3n3	Control	52	0.315	0.033	0.246	0.246	0.234		
		DHA	58	0.257	0.014	0.216	0.216			
		DHA+ARA	61	0.233	0.010					
Study Form Initiation	20:1	Control	52	0.287	0.020	0.262	0.262	0.723		
		DHA	58	0.287	0.015	0.281	0.281			
		DHA+ARA	61	0.268	0.011	0.269	0.269			
Study Form Initiation	18:4	Control	52	0.017	0.003	0.000	0.000	0.290		
		DHA	58	0.025	0.004	0.017	0.017			
		DHA+ARA	61	0.017	0.003	0.008	0.008			
Study Form Initiation	20:2n6	Control	52	0.632	0.025	0.632	0.632	0.673		
		DHA	58	0.528	0.025	0.640	0.640			
		DHA+ARA	61	0.602	0.021	0.614	0.614			
Study Form Initiation	20:3n6	Control	52	2.144	0.098	2.096	2.096	0.507		
		DHA	58	2.208	0.080	2.296	2.296			
		DHA+ARA	61	2.218	0.074	2.135	2.135			
Study Form Initiation	20:4n6	Control	52	7.657	0.262	8.124	8.124	0.819		
		DHA	58	8.164	0.347	7.876	7.876			
		DHA+ARA	61	8.090	0.310	8.207	8.207			
Study Form Initiation	22:1	Control	52	0.106	0.010	0.105	0.105	0.155		
		DHA	58	0.127	0.010	0.130	0.130			
		DHA+ARA	61	0.126	0.010	0.139	0.139			
Study Form Initiation	20:5n3	Control	52	0.351	0.057	0.298	0.298	0.911		
		DHA	58	0.322	0.015	0.302	0.302			
		DHA+ARA	61	0.321	0.015	0.329	0.329			

Table 9

Red Blood Cell Phosphatidylcholine Fatty Acids

Time	Fatty Acid	Regimen	n	Arithmetinc Mean	Standard Error	Regimen p-value	Pairwise Comparison	Pairwise p-value
Study Form Initiation	22:4n6	Control	52	0.578	0.144	0.423	0.331	0.331
		DHA	58	0.493	0.030	0.481		
		DHA+ARA	61	0.443	0.021	0.425		
Study Form Initiation	24:1	Control	52	0.208	0.054	0.075	0.665	0.665
		DHA	58	0.115	0.019	0.084		
		DHA+ARA	61	0.180	0.056	0.096		
Study Form Initiation	22:5n6	Control	52	0.266	0.020	0.232	0.923	0.923
		DHA	58	0.259	0.017	0.239		
		DHA+ARA	61	0.265	0.018	0.256		
Study Form Initiation	22:4n3	Control	52	0.000	0.000	0.000	0.199	0.199
		DHA	58	0.001	0.001	0.000		
		DHA+ARA	61	0.002	0.001	0.000		
Study Form Initiation	22:5n3	Control	52	0.213	0.019	0.203	0.885	0.885
		DHA	58	0.215	0.013	0.195		
		DHA+ARA	61	0.203	0.010	0.193		
Study Form Initiation	22:6n3	Control	52	0.984	0.051	1.000	0.858	0.858
		DHA	58	1.075	0.053	1.034		
		DHA+ARA	61	1.006	0.050	0.970		

- 36 -

Table 9
Red Blood Cell Phosphatidylcholine Fatty Acids

Time	Fatty Acid	Red Blood Cell Phosphatidylcholine Fatty Acids					Pairwise Comparison	Pairwise p-value
		Regimen	n	Arithmetic Mean	Standard Error	Median		
Study Form Termination	12:0	Control	53	0.100	0.026	0.035	0.843	
		DHA	56	0.111	0.042	0.031		
		DHA+ARA	59	0.064	0.012	0.032		
Study Form Termination	14:0	Control	53	0.808	0.039	0.806	0.834	
		DHA	56	0.781	0.035	0.783		
		DHA+ARA	59	0.755	0.036	0.758		
Study Form Termination	14:1	Control	53	0.047	0.008	0.033	0.155	
		DHA	56	0.036	0.009	0.015		
		DHA+ARA	59	0.036	0.007	0.018		
Study Form Termination	16:0	Control	53	35.837	0.512	34.798	0.767	
		DHA	56	35.560	0.595	34.861		
		DHA+ARA	59	35.069	0.584	33.890		
Study Form Termination	16:1	Control	53	0.566	0.026	0.526	0.013	
		DHA	56	0.594	0.042	0.475		
		DHA+ARA	59	0.526	0.029	0.472		
Study Form Termination	18:0	Control	53	13.972	0.261	14.197	0.886	
		DHA	56	14.065	0.237	13.867		
		DHA+ARA	59	14.341	0.253	14.108		
Study Form Termination	18:1	Control	53	14.456	0.277	14.291	0.686	
		DHA	56	14.116	0.272	13.998		
		DHA+ARA	59	14.344	0.380	14.218		
Study Form Termination	18:2	Control	53	21.673	0.340	21.506	0.001	
		DHA	56	22.065	0.457	22.517		
		DHA+ARA	59	19.899	0.337	20.662		
Study Form Termination	18:3n6	Control	53	0.080	0.006	0.074	0.527	
		DHA	56	0.088	0.009	0.076		
		DHA+ARA	59	0.087	0.013	0.066		

Table 9
Red Blood Cell Phosphatidylcholine Fatty Acids

Fatty Acid	Time	Regimen	n	Arithmetic Mean	Standard Error	Median	Regimen p-value	Pairwise Comparison	Pairwise p-value
Study Form Termination 20:0	18:3n3	Control	53	0.504	0.050	0.392	0.424	Control vs DHA Control vs DHA+ARA DHA vs DHA+ARA	0.503 0.068 0.011
		DHA	56	0.472	0.053	0.281			
		DHA+ARA	59	0.430	0.069	0.251			
Study Form Termination 20:1	18:4	Control	53	0.321	0.020	0.283	0.031	Control vs DHA Control vs DHA+ARA DHA vs DHA+ARA	0.672 0.015 0.008
		DHA	56	0.335	0.030	0.285			
		DHA+ARA	59	0.273	0.009	0.256			
Study Form Termination 20:2n6	20:3n6	Control	53	0.318	0.014	0.302	0.149	Control vs DHA Control vs DHA+ARA DHA vs DHA+ARA	0.004 0.003 0.002
		DHA	56	0.300	0.013	0.283			
		DHA+ARA	59	0.307	0.013	0.283			
Study Form Termination 20:4n6	20:4n6	Control	53	0.022	0.004	0.015	0.672	Control vs DHA Control vs DHA+ARA DHA vs DHA+ARA	0.051 0.018 0.008
		DHA	56	0.022	0.003	0.018			
		DHA+ARA	59	0.014	0.002	0.018			
Study Form Termination 20:5n3	20:5n3	Control	53	0.893	0.026	0.910	0.051	Control vs DHA Control vs DHA+ARA DHA vs DHA+ARA	0.004 0.003 0.002
		DHA	56	0.880	0.023	0.873			
		DHA+ARA	59	0.824	0.022	0.821			
Study Form Termination 22:1	22:1	Control	53	2.032	0.073	2.091	0.208	Control vs DHA Control vs DHA+ARA DHA vs DHA+ARA	0.097 0.000 0.000
		DHA	56	2.017	0.070	2.043			
		DHA+ARA	59	1.908	0.064	1.904			
Study Form Termination 22:6	22:6	Control	53	6.046	0.240	6.029	0.000	Control vs DHA Control vs DHA+ARA DHA vs DHA+ARA	0.000 0.000 0.000
		DHA	56	5.774	0.220	5.892			
		DHA+ARA	59	8.465	0.255	8.891			
Study Form Termination 24:0	24:0	Control	53	0.117	0.010	0.125	0.946	Control vs DHA Control vs DHA+ARA DHA vs DHA+ARA	0.004 0.108 0.000
		DHA	56	0.110	0.009	0.114			
		DHA+ARA	59	0.115	0.011	0.104			

- 38 -

Table 9
Red Blood Cell Phosphatidylcholine Fatty Acids

Time	Fatty Acid	Regimen	n	Arithmetic Mean		Regimen p-value	Pairwise Comparison	Pairwise p-value
				Standard Error	Median			
Study Form Termination	22:4n6	Control	53	0.486	0.048	0.390	Control vs DHA+ARA	0.093
		DHA	56	0.489	0.061	0.426		
		DHA+ARA	59	0.496	0.027	0.487		
Study Form Termination	24:1	Control	53	0.127	0.039	0.062	Control vs DHA+ARA	0.303
		DHA	56	0.143	0.036	0.086		
		DHA+ARA	59	0.177	0.040	0.089		
Study Form Termination	22:5n6	Control	53	0.181	0.013	0.163	Control vs DHA+ARA	0.005
		DHA	56	0.145	0.011	0.133		
		DHA+ARA	59	0.172	0.009	0.165		
Study Form Termination	22:4n3	Control	53	0.001	0.001	0.000	Control vs DHA+ARA	0.895
		DHA	56	0.001	0.001	0.000		
		DHA+ARA	59	0.003	0.002	0.000		
Study Form Termination	22:5n3	Control	53	0.306	0.019	0.289	Control vs DHA+ARA	0.006
		DHA	56	0.293	0.026	0.260		
		DHA+ARA	59	0.265	0.013	0.255		
Study Form Termination	22:6n3	Control	53	0.895	0.072	0.812	Control vs DHA+ARA	0.000
		DHA	56	1.380	0.063	1.352		
		DHA+ARA	59	1.244	0.049	1.259		

- 39 -

Table 9
Red Blood Cell Phosphatidylcholine Fatty Acids

Time	Fatty Acid	Regimen	Arithmetic Mean			Regimen p-value	Pairwise Comparison	Pairwise p-value
			n	Standard Error	Median			
48 Weeks PCA	12:0	Control	37	0.032	0.005	0.026	0.729	
		DHA	32	0.028	0.006	0.016		
		DHA+ARA	38	0.026	0.006	0.021		
		HM	56	0.059	0.016	0.020		
48 Weeks PCA	14:0	Control	37	0.402	0.039	0.331	0.943	
		DHA	32	0.353	0.032	0.324		
		DHA+ARA	38	0.353	0.026	0.328		
		HM	56	0.381	0.026	0.335		
48 Weeks PCA	14:1	Control	37	0.025	0.006	0.013	0.448	
		DHA	32	0.026	0.007	0.011		
		DHA+ARA	38	0.026	0.006	0.015		
		HM	56	0.024	0.003	0.020		
48 Weeks PCA	16:0	Control	37	34.627	0.577	34.319	0.000	
		DHA	32	35.272	0.689	34.473		
		DHA+ARA	38	34.802	0.506	34.165		
		HM	56	33.037	0.506	32.228		
48 Weeks PCA	16:1	Control	37	0.435	0.043	0.338	0.000	
		DHA	32	0.380	0.023	0.352		
		DHA+ARA	38	0.395	0.024	0.368		
		HM	56	0.507	0.020	0.473		

Table 9

Red Blood Cell Phosphatidylcholine Fatty Acids							
Time	Fatty Acid	Regimen	n	Arithmetic Mean	Standard Error	Median	Regimen p-value
48 Weeks PCA	18:0	Control	37	13.016	0.313	12.759	0.000
		DHA	32	12.944	0.269	12.786	Control vs DHA 0.760
		DHA+ARA	38	12.804	0.235	12.793	Control vs DHA+ARA 0.889
		HH	56	14.583	0.287	14.729	HH vs DHA 0.000 HH vs DHA+ARA 0.000 Control vs HH 0.000 DHA vs DHA+ARA 0.661
48 Weeks PCA	18:1	Control	37	17.894	0.453	18.636	0.256
		DHA	32	17.766	0.429	18.492	
		DHA+ARA	38	17.850	0.289	18.227	
		HH	56	18.662	0.305	18.727	
48 Weeks PCA	18:2	Control	37	23.469	0.518	23.552	0.000
		DHA	32	23.538	0.516	23.717	Control vs DHA 0.840
		DHA+ARA	38	23.738	0.422	23.839	Control vs DHA+ARA 0.527
		HH	56	18.650	0.344	18.482	HH vs DHA 0.000 HH vs DHA+ARA 0.000 Control vs HH 0.000 DHA vs DHA+ARA 0.685
48 Weeks PCA	18:3n6	Control	37	0.071	0.008	0.061	0.002
		DHA	32	0.069	0.005	0.067	Control vs DHA 0.950
		DHA+ARA	38	0.069	0.006	0.062	Control vs DHA+ARA 0.774
		HH	56	0.042	0.004	0.039	HH vs DHA 0.004 HH vs DHA+ARA 0.001 Control vs HH 0.003 DHA vs DHA+ARA 0.831
48 Weeks PCA	20:0	Control	37	0.348	0.075	0.197	0.785
		DHA	32	0.339	0.061	0.206	
		DHA+ARA	38	0.304	0.061	0.172	
		HH	56	0.409	0.044	0.215	

Table 9

Red Blood Cell Phosphatidylcholine Fatty Acids								
Time	Fatty Acid	Regimen	n	Arithmetic Mean	Standard Error	Regimen p-value	Pairwise Comparison	
48 Weeks PCA	18:3n3	Control	37	0.222	0.019	0.182	0.001	
		DHA	32	0.211	0.015	0.182	Control vs DHA	
		DHA+ARA	38	0.203	0.010	0.190	Control vs DHA+ARA	
		HM	56	0.182	0.022	0.120	HM vs DHA+ARA	
48 Weeks PCA	20:1	Control	37	0.418	0.019	0.420	0.000	
		DHA	32	0.406	0.025	0.435	Control vs DHA	
		DHA+ARA	38	0.382	0.016	0.375	Control vs DHA+ARA	
		HM	56	0.311	0.014	0.309	HM vs DHA+ARA	
48 Weeks PCA	18:4	Control	37	0.018	0.005	0.000	0.010	
		DHA	32	0.016	0.004	0.000	Control vs DHA	
		DHA+ARA	38	0.007	0.002	0.000	Control vs DHA+ARA	
		HM	56	0.024	0.004	0.015	HM vs DHA+ARA	
48 Weeks PCA	20:2n6	Control	37	0.543	0.023	0.537	0.629	
		DHA	32	0.557	0.032	0.543	Control vs DHA	
		DHA+ARA	38	0.636	0.053	0.550	Control vs DHA+ARA	
		HM	56	0.560	0.014	0.531	HM vs DHA+ARA	
48 Weeks PCA	20:3n6	Control	37	1.709	0.086	1.741	0.000	
		DHA	32	1.702	0.073	1.684	Control vs DHA	
		DHA+ARA	38	1.844	0.090	1.717	HM vs DHA+ARA	
		HM	56	2.265	0.086	2.166	Control vs HM	
							DHA vs DHA+ARA	

- 42 -

Table 9

Red Blood Cell Phosphatidylcholine Fatty Acids						
Time	Fatty Acid	Regimen	n	Arithmetic Mean	Standard Error	Median
48 Weeks PCA	20:4n6	Control	37	4.738	0.255	4.736
	DHA	32	4.475	0.196	4.499	0.000
	DHA+ARA	38	4.550	0.185	4.766	Control vs DHA Control vs DHA+ARA HM vs DHA HM vs DHA+ARA
	HM	56	7.408	0.250	7.666	Control vs HM DHA vs HM DHA vs DHA+ARA
48 Weeks PCA	22:1	Control	37	0.166	0.036	0.131
	DHA	32	0.116	0.014	0.118	0.664
	DHA+ARA	38	0.131	0.024	0.105	
	HM	56	0.160	0.030	0.104	
48 Weeks PCA	20:5n3	Control	37	0.102	0.015	0.077
	DHA	32	0.084	0.006	0.083	0.633
	DHA+ARA	38	0.099	0.009	0.078	Control vs DHA+ARA HM vs DHA HM vs DHA+ARA
	HM	56	0.138	0.009	0.123	Control vs HM DHA vs HM DHA vs DHA+ARA
48 Weeks PCA	22:4n6	Control	37	0.426	0.059	0.373
	DHA	32	0.382	0.029	0.417	0.244
	DHA+ARA	38	0.440	0.054	0.384	
	HM	56	0.406	0.022	0.377	
48 Weeks PCA	24:1	Control	37	0.247	0.070	0.112
	DHA	32	0.210	0.062	0.116	0.000
	DHA+ARA	38	0.179	0.055	0.108	Control vs DHA Control vs DHA+ARA HM vs DHA HM vs DHA+ARA
	HM	56	0.115	0.020	0.079	Control vs HM DHA vs HM DHA vs DHA+ARA

- 43 -

Table 9

Red Blood Cell Phosphatidylcholine Fatty Acids

Time	Fatty Acid	Regimen	n	Arithmetic Mean		Median	Regimen p-value	Pairwise Comparison	Pairwise p-value
				Standard Error	p-value				
48 Weeks PCA	22:5n6	Control	37	0.210	0.016	0.212	0.000	Control vs DHA	0.505
		DHA	32	0.189	0.012	0.186		Control vs DHA+ARA	0.647
		DHA+ARA	38	0.231	0.022	0.198		HN vs DHA	0.000
		HM	56	0.264	0.016	0.265		HN vs DHA+ARA	0.001
48 Weeks PCA	22:4n3	Control	37	0.000	0.000	0.000	0.000	Control vs HM	0.000
		DHA	32	0.000	0.000	0.000		DHA vs DHA+ARA	0.270
		DHA+ARA	38	0.000	0.000	0.000			
		HM	56	0.000	0.000	0.000			
48 Weeks PCA	22:5n3	Control	37	0.286	0.029	0.260	0.000	Control vs DHA	0.598
		DHA	32	0.253	0.017	0.251		Control vs DHA+ARA	0.759
		DHA+ARA	38	0.268	0.026	0.256		HN vs DHA	0.000
		HM	56	0.339	0.018	0.314		HN vs DHA+ARA	0.000
48 Weeks PCA	22:6n3	Control	37	0.595	0.047	0.569	0.000	Control vs HM	0.000
		DHA	32	0.685	0.048	0.676		DHA vs DHA+ARA	0.817
		DHA+ARA	38	0.662	0.043	0.663			
		HM	56	1.475	0.081	1.333			

-44-

Table 10
Red Blood Cell Phosphatidylethanolamine Fatty Acids

		Fatty Acid	Regimen	n	Arithmetic Mean	Standard Error	Median	Regimen p-value	Pairwise Comparison	Pairwise p-value
Study Form Initiation	12:0	Control	52	0.069	0.015	0.022	0.033	0.546		
		DHA	57	0.075	0.013	0.033	0.039			
		DHA+ARA	61	0.063	0.010					
Study Form Initiation	14:0	Control	52	0.307	0.038	0.220	0.206	0.792		
		DHA	57	0.278	0.025	0.246	0.246			
		DHA+ARA	61	0.277	0.021					
Study Form Initiation	14:1	Control	52	0.080	0.015	0.032	0.028	0.181		
		DHA	57	0.061	0.012	0.050	0.050			
		DHA+ARA	61	0.062	0.009					
Study Form Initiation	16:0	Control	52	20.021	0.736	17.945	19.295	0.967		
		DHA	57	19.867	0.622	19.035	19.035			
		DHA+ARA	61	19.796	0.451					
Study Form Initiation	16:1	Control	52	0.731	0.035	0.698	0.746	0.337		
		DHA	57	0.769	0.034	0.837	0.837			
		DHA+ARA	61	0.836	0.035					
Study Form Initiation	18:0	Control	52	8.857	0.329	8.469	8.308	0.142		
		DHA	57	8.434	0.227	7.904	7.904			
		DHA+ARA	61	8.201	0.215					
Study Form Initiation	18:1	Control	52	16.450	0.301	16.698	16.308	0.412		
		DHA	57	16.208	0.326	16.001	16.001			
		DHA+ARA	61	16.415	0.375					
Study Form Initiation	18:2	Control	52	6.615	0.253	6.682	6.366	0.773		
		DHA	57	6.336	0.280	5.682	5.682			
		DHA+ARA	61	6.175	0.294					
Study Form Initiation	18:3n6	Control	52	0.165	0.018	0.165	0.152	0.373	Control vs DHA+ARA	0.013
		DHA	57	0.190	0.019	0.169	0.169		Control vs DHA+ARA	0.101
		DHA+ARA	61	0.192	0.016					

- 45 -

Table 10
Red Blood Cell Phosphatidylethanolamine Fatty Acids

		Fatty Acid	Regimen	n	Arithmetic Mean	Standard Error	Median	Regimen p-value	Pairwise Comparison	Pairwise p-value
Study Form Initiation	20:0	Control	52	0.372	0.043	0.291	0.151			
		DHA	57	0.316	0.030	0.244				
		DHA+ARA	61	0.259	0.024	0.166				
Study Form Initiation	18:3n3	Control	52	0.305	0.023	0.261	0.641			
		DHA	57	0.269	0.018	0.249				
		DHA+ARA	61	0.257	0.016	0.225				
Study Form Initiation	20:1	Control	52	0.573	0.036	0.517	0.395			
		DHA	57	0.615	0.034	0.555				
		DHA+ARA	61	0.571	0.027	0.544				
Study Form Initiation	18:4	Control	52	0.025	0.005	0.000	0.371			
		DHA	57	0.031	0.006	0.025				
		DHA+ARA	61	0.030	0.007	0.021				
Study Form Initiation	20:2n6	Control	52	0.479	0.023	0.480	0.706			
		DHA	57	0.663	0.024	0.437				
		DHA+ARA	61	0.443	0.028	0.427				
Study Form Initiation	20:3n6	Control	52	1.863	0.072	1.829	0.099			
		DHA	57	1.965	0.077	1.820				
		DHA+ARA	61	1.973	0.064	1.911				
Study Form Initiation	20:4n6	Control	52	25.817	0.618	26.820	0.353			
		DHA	57	26.475	0.611	27.376				
		DHA+ARA	61	26.747	0.615	27.708				
Study Form Initiation	22:1	Control	52	0.150	0.017	0.138	0.572			
		DHA	57	0.167	0.015	0.151				
		DHA+ARA	61	0.168	0.017	0.141				
Study Form Initiation	20:5n3	Control	52	0.378	0.024	0.357	0.997			
		DHA	57	0.384	0.024	0.370				
		DHA+ARA	61	0.366	0.022	0.335				

Table 10
Red Blood Cell Phosphatidylethanolamine Fatty Acids

Time	Fatty Acid	Regimen	n	Arithmetic Mean	Standard Error	Regimen p-value	Pairwise Comparison	Pairwise p-value
Study Form Initiation	22:4n6	Control	52	7.290	0.182	7.402	0.875	0.068
		DHA	57	7.431	0.186	7.538		
		DHA+ARA	61	7.456	0.167	7.270		
Study Form Initiation	24:1	Control	52	0.100	0.028	0.061	0.031	0.047
		DHA	57	0.059	0.009	0.031		
		DHA+ARA	61	0.072	0.010	0.067		
Study Form Initiation	22:5n6	Control	52	1.757	0.083	1.782	0.555	1.857
		DHA	57	1.809	0.070	1.775		
		DHA+ARA	61	1.851	0.075	1.775		
Study Form Initiation	22:4n3	Control	52	0.001	0.001	0.000	0.257	0.000
		DHA	57	0.001	0.001	0.000		
		DHA+ARA	61	0.005	0.002	0.000		
Study Form Initiation	22:5n3	Control	52	1.496	0.109	1.308	0.195	0.988
		DHA	57	1.375	0.109	1.061		
		DHA+ARA	61	1.380	0.097	1.061		
Study Form Initiation	22:6n3	Control	52	6.119	0.200	6.381	0.375	6.468
		DHA	57	6.444	0.185	6.220		
		DHA+ARA	61	6.407	0.220	6.579		

Table 10
Red Blood Cell Phosphatidylethanolamine Fatty Acids

Time	Fatty Acid	Red Blood Cell Phosphatidylethanolamine Fatty Acids					Pairwise Comparison	Pairwise p-value
		Regimen	n	Arithmetic Mean	Standard Error	Median		
Study Form Termination	12:0	Control	53	0.093	0.018	0.033	0.630	
		DHA	55	0.093	0.019	0.036		
		DHA+ARA	58	0.067	0.012	0.035		
Study Form Termination	14:0	Control	53	0.360	0.031	0.279	0.782	
		DHA	55	0.380	0.039	0.265		
		DHA+ARA	58	0.348	0.030	0.256		
Study Form Termination	14:1	Control	53	0.086	0.020	0.041	0.592	
		DHA	55	0.066	0.013	0.000		
		DHA+ARA	58	0.066	0.011	0.043		
Study Form Termination	16:0	Control	53	19.326	0.673	17.617	0.560	
		DHA	55	19.062	0.614	17.556		
		DHA+ARA	58	18.357	0.467	17.568		
Study Form Termination	16:1	Control	53	0.511	0.034	0.476	0.604	
		DHA	55	0.579	0.045	0.509		
		DHA+ARA	58	0.618	0.049	0.555		
Study Form Termination	18:0	Control	53	9.614	0.266	9.406	0.024	
		DHA	55	9.173	0.208	8.818		
		DHA+ARA	58	8.961	0.242	8.697		
Study Form Termination	18:1	Control	53	14.763	0.437	14.695	0.333	
		DHA	55	15.177	0.299	14.927		
		DHA+ARA	58	14.814	0.330	14.499		
Study Form Termination	18:2	Control	53	9.405	0.192	9.359	0.000	
		DHA	55	9.180	0.207	9.188		
		DHA+ARA	58	7.756	0.141	7.586		
Study Form Termination	18:3:6	Control	53	0.169	0.012	0.163	0.160	
		DHA	55	0.187	0.017	0.157		
		DHA+ARA	58	0.198	0.018	0.161		

Table 10
Red Blood Cell Phosphatidylethanolamine Fatty Acids

Time	Fatty Acid	Regimen	n	Arithmetic Mean		Median	Regimen p-value	Pairwise Comparison	Pairwise P-value
				Standard Error	n				
Study Form Termination 20:0	Control	53	0.404	0.044	0.278	0.146	0.146	0.136	0.136
	DHA	55	0.336	0.037	0.208	0.208			
	DHA+ARA	58	0.288	0.029	0.208	0.208			
Study Form Termination 18:3n3	Control	53	0.382	0.017	0.364	0.364	0.164	0.164	0.164
	DHA	55	0.368	0.016	0.354	0.354			
	DHA+ARA	58	0.329	0.015	0.305	0.305			
Study Form Termination 20:1	Control	53	0.553	0.029	0.526	0.526	0.164	0.164	0.164
	DHA	55	0.579	0.028	0.537	0.537			
	DHA+ARA	58	0.507	0.025	0.483	0.483			
Study Form Termination 18:4	Control	53	0.042	0.010	0.018	0.018	0.108	0.108	0.108
	DHA	55	0.026	0.005	0.019	0.019			
	DHA+ARA	58	0.022	0.004	0.000	0.000			
Study Form Termination 20:2n6	Control	53	0.754	0.029	0.765	0.765	0.068	0.068	0.068
	DHA	55	0.774	0.030	0.750	0.750			
	DHA+ARA	58	0.654	0.026	0.663	0.663			
Study Form Termination 20:3n6	Control	53	2.253	0.111	2.073	2.073	0.203	0.203	0.203
	DHA	55	2.295	0.094	2.206	2.206			
	DHA+ARA	58	2.066	0.073	1.992	1.992			
Study Form Termination 20:4n6	Control	53	24.279	0.527	25.132	0.000	0.119	0.119	0.119
	DHA	55	23.464	0.520	24.038	0.000			
	DHA+ARA	58	26.760	0.437	27.372	0.000			
Study Form Termination 22:1	Control	53	0.149	0.019	0.122	0.229	0.000	0.000	0.000
	DHA	55	0.176	0.016	0.169	0.169			
	DHA+ARA	58	0.146	0.012	0.130	0.130			
Study Form Termination 20:5n3	Control	53	0.519	0.020	0.493	0.000	0.286	0.286	0.286
	DHA	55	0.563	0.025	0.575	0.000			
	DHA+ARA	58	0.411	0.015	0.415	0.000			

Table 10
Red Blood Cell Phosphatidylethanolamine Fatty Acids

Time	Fatty Acid	Regimen	n	Arithmet ic Mean	Standard Error	Median	Regimen p-value	Pairwise Comparison	Pairwise p-value
Study Form Termination	22:4n6	Control	53	7.309	0.208	7.656	0.007	Control vs DHA	0.025
		DHA	55	7.135	0.154	6.885		Control vs DHA+ARA	0.461
		DHA+ARA	58	7.592	0.155	7.635		DHA vs DHA+ARA	0.002
Study Form Termination	24:1	Control	53	0.092	0.023	0.038	0.294		
		DHA	55	0.056	0.009	0.042			
		DHA+ARA	58	0.062	0.008	0.041			
Study Form Termination	22:5n6	Control	53	1.444	0.064	1.423	0.010	Control vs DHA	0.003
		DHA	55	1.231	0.034	1.213		Control vs DHA+ARA	0.255
		DHA+ARA	58	1.347	0.040	1.330		DHA vs DHA+ARA	0.050
Study Form Termination	22:4n3	Control	53	0.000	0.000	0.000	0.137		
		DHA	55	0.004	0.002	0.000			
		DHA+ARA	58	0.004	0.002	0.000			
Study Form Termination	22:5n3	Control	53	2.694	0.110	2.839	0.003	Control vs DHA	0.004
		DHA	55	2.334	0.091	2.400		Control vs DHA+ARA	0.002
		DHA+ARA	58	2.237	0.069	2.269		DHA vs DHA+ARA	0.943
Study Form Termination	22:6n3	Control	53	4.798	0.151	4.815	0.000	Control vs DHA	0.000
		DHA	55	6.762	0.183	7.043		Control vs DHA+ARA	0.000
		DHA+ARA	58	6.389	0.150	6.498		DHA vs DHA+ARA	0.027

-50-

Table 10

Red Blood Cell Phosphatidylethanolamine Fatty Acids							
Time	Fatty Acid	Regimen	n	Arithmetic Mean	Standard Error	Median	Regimen p-value
48 Weeks PCA	12:0	Control	37	0.053	0.019	0.024	0.587
		DHA	32	0.054	0.016	0.019	
		DHA+ARA	38	0.047	0.014	0.018	
		HM	56	0.045	0.011	0.023	
48 Weeks PCA	14:0	Control	37	0.243	0.030	0.169	0.598
		DHA	32	0.251	0.041	0.162	
		DHA+ARA	38	0.235	0.025	0.188	
		HM	56	0.230	0.016	0.210	
48 Weeks PCA	14:1	Control	37	0.080	0.017	0.037	0.092
		DHA	32	0.055	0.017	0.000	
		DHA+ARA	38	0.078	0.019	0.044	
		HM	56	0.053	0.011	0.021	
48 Weeks PCA	16:0	Control	37	17.319	0.595	16.314	0.177
		DHA	32	17.101	0.729	15.692	
		DHA+ARA	38	17.225	0.538	16.997	
		HM	56	18.138	0.395	17.607	
48 Weeks PCA	16:1	Control	37	0.440	0.050	0.349	0.000
		DHA	32	0.390	0.035	0.336	0.601
		DHA+ARA	38	0.390	0.022	0.376	0.324
		HM	56	0.596	0.027	0.562	0.000
		Control					HM vs DHA+ARA
		DHA					Control vs HM
		DHA+ARA					HM vs DHA
		HM					Control vs DHA
		HM					DHA vs DHA+ARA
		DHA					Control vs DHA
		DHA+ARA					HM vs DHA
		HM					Control vs DHA

-51-

Table 10
Red Blood Cell Phosphatidylethanolamine Fatty Acids

Time	Fatty Acid	Regimen	n	Arithmetic Mean	Standard Error	Median	Regimen p-value	Pairwise P value	
								Control vs DHA	DHA vs DHA+ARA
48 Weeks PCA	18:0	Control	37	7.935	0.327	7.174	0.000	Control vs DHA	0.347
		DHA	32	7.962	0.293	7.552		Control vs DHA+ARA	0.483
		DHA+ARA	38	7.443	0.270	7.173		HM vs DHA	0.020
		HM	56	8.754	0.230	8.409		HM vs DHA+ARA	0.000
48 Weeks PCA	18:1	Control	37	19.438	0.368	19.410	0.038	Control vs DHA	0.401
		DHA	32	19.066	0.421	19.534		Control vs DHA+ARA	0.234
		DHA+ARA	38	19.302	0.332	19.433		HM vs DHA	0.067
		HM	56	18.469	0.278	18.141		HM vs DHA+ARA	0.118
48 Weeks PCA	18:2	Control	37	9.328	0.261	9.267	0.000	Control vs DHA	0.024
		DHA	32	8.867	0.210	8.696		Control vs DHA+ARA	0.187
		DHA+ARA	38	9.257	0.216	8.840		HM vs DHA	0.000
		HM	56	6.291	0.193	6.027		HM vs DHA+ARA	0.000
48 Weeks PCA	18:3n6	Control	37	0.198	0.020	0.182	0.050	Control vs DHA	0.879
		DHA	32	0.219	0.031	0.171		Control vs DHA+ARA	0.590
		DHA+ARA	38	0.188	0.021	0.158		HM vs DHA	0.029
		HM	56	0.129	0.012	0.112		HM vs DHA+ARA	0.061
48 Weeks PCA	20:0	Control	37	0.263	0.058	0.146	0.728	Control vs HM	0.014
		DHA	32	0.262	0.042	0.145		DHA vs DHA+ARA	0.714
		DHA+ARA	38	0.212	0.037	0.125			
		HM	56	0.295	0.031	0.240			

-52-

Table 10
Red Blood Cell Phosphatidylethanolamine Fatty Acids

		Fatty Acid	Regimen	n	Arithmet ic Mean	Standard Error	Median	Regimen P-value	Pairwise Comparison	Pairwise p-value
48 Weeks PCA	18:3n3	Control	37	0.291	0.025	0.125	0.001	Control vs DHA	0.559	
		DHA	32	0.270	0.017	0.262		Control vs DHA+ARA	0.848	
		DHA+ARA	38	0.265	0.015	0.245		HM vs DHA	0.008	
		HM	56	0.226	0.020	0.169		HM vs DHA+ARA	0.002	
48 Weeks PCA	20:1	Control	37	0.715	0.031	0.648	0.000	Control vs HM	0.001	
		DHA	32	0.772	0.032	0.782		Control vs DHA+ARA	0.689	
		DHA+ARA	38	0.936	0.188	0.738		HM vs DHA		
		HM	56	0.533	0.024	0.492		HM vs DHA+ARA		
48 Weeks PCA	18:4	Control	37	0.017	0.005	0.003	0.057	Control vs HM	0.000	
		DHA	32	0.017	0.005	0.000		Control vs DHA+ARA	0.000	
		DHA+ARA	38	0.023	0.006	0.000		HM vs DHA+ARA	0.000	
		HM	56	0.027	0.004	0.019		DHA vs DHA+ARA	0.115	
48 Weeks PCA	20:2n6	Control	37	0.672	0.035	0.698	0.000	Control vs DHA	0.543	
		DHA	32	0.668	0.026	0.684		Control vs DHA+ARA	0.532	
		DHA+ARA	38	0.715	0.032	0.689		HM vs DHA	0.000	
		HM	56	0.444	0.016	0.412		HM vs DHA+ARA	0.000	
48 Weeks PLA	20:3n6	Control	37	2.138	0.099	1.999	0.012	Control vs HM	0.000	
		DHA	32	2.165	0.100	2.045		Control vs DHA+ARA	0.935	
		DHA+ARA	38	2.172	0.114	2.132		HM vs DHA	0.015	
		HM	56	1.715	0.053	1.637		HM vs DHA+ARA	0.006	
								Control vs HM	0.007	
								DHA vs DHA+ARA	0.835	

-53-

Table 10
Red Blood Cell Phosphatidylethanolamine Fatty Acids

Time	Fatty Acid	Regimen	n	Arithmetic Mean			Median	Regimen p-value	Pairwise comparison	Pairwise p-value
				Standard Error						
48 Weeks PCA	20:4n6	Control	37	24.508	0.536	24.774	0.950			
		DHA	32	24.428	0.491	25.006				
		DHA+ARA	38	24.788	0.429	25.122				
		HM	56	24.625	0.384	25.189				
48 Weeks PCA	22:1	Control	37	0.168	0.016	0.172	0.121			
		DHA	32	0.189	0.022	0.188				
		DHA+ARA	38	0.154	0.022	0.133				
		HM	56	0.148	0.013	0.134				
48 Weeks PCA	20:5n3	Control	37	0.382	0.026	0.368	0.497			
		DHA	32	0.369	0.015	0.377				
		DHA+ARA	38	0.347	0.011	0.347				
		HM	56	0.384	0.016	0.360				
48 Weeks PCA	22:4n6	Control	37	8.580	0.267	8.761	0.001			
		DHA	32	8.791	0.250	9.132				
		DHA+ARA	38	8.576	0.188	8.472				
		HM	56	7.727	0.203	7.618				
48 Weeks PCA	24:1	Control	37	0.067	0.016	0.035	0.943			
		DHA	32	0.049	0.009	0.034				
		DHA+ARA	38	0.046	0.008	0.036				
		HM	56	0.062	0.016	0.027				

-54-

Table 10
Red Blood Cell Phosphatidylethanolamine Fatty Acids

Time	Fatty Acid	Regimen	n	Arithmetic Mean			Median	Regimen p-value	Pairwise Comparison		Pairwise p-value
				Standard Error							
48 Weeks PCA	22:5n6	Control	37	1.401	0.066	1.411	0.000		Control vs DHA	0.977	
		DHA	32	1.353	0.057	1.414			Control vs DHA+ARA	0.997	
		DHA+ARA	38	1.364	0.054	1.359			HM vs DHA	0.000	
		HM	56	1.883	0.056	1.889			HM vs DHA+ARA	0.000	
48 Weeks PCA	22:6n3	Control	37	0.000	0.000	0.000	0.000		Control vs HM	0.000	
		DHA	32	0.000	0.000	0.000	0.000		DHA vs HM	0.975	
		DHA+ARA	38	0.000	0.000	0.000	0.000		DHA+ARA vs HM	0.000	
		HM	56	0.001	0.001	0.000	0.000		DHA+ARA vs DHA	0.975	
48 Weeks PCA	22:5n3	Control	37	2.567	0.092	2.681	0.000		Control vs DHA	0.884	
		DHA	32	2.561	0.086	2.630			Control vs DHA+ARA	0.148	
		DHA+ARA	38	2.636	0.066	2.643			HM vs DHA	0.000	
		HM	56	1.942	0.065	1.978			HM vs DHA+ARA	0.000	
48 Weeks PCA	22:6n3	Control	37	3.196	0.159	3.013	0.000		Control vs HM	0.000	
		DHA	32	4.143	0.177	4.079			DHA vs HM	0.000	
		DHA+ARA	38	3.801	0.134	3.721			HM vs DHA+ARA	0.000	
		HM	56	7.283	0.201	7.341			Control vs DHA	0.000	
									DHA vs DHA+ARA	0.281	

-55-

Table 11
Preterm Infant Complications

	Regimen			p-value*
	Control	DHA	DHA+ARA	
Retinopathy of Prematurity Test Results				
Absent	34 (76%)	44 (76%)	41 (79%)	0.91
I	8 (18%)	11 (19%)	6 (12%)	
II	2 (4%)	2 (3%)	4 (8%)	
III	1 (2%)	1 (2%)	1 (2%)	
Present, but not graded				
Ultrasound Examination for Intraventricular Hemorrhage				
None	47 (81%)	52 (84%)	49 (80%)	0.78
Stage 1	6 (10%)	9 (15%)	7 (11%)	
Stage 2	3 (5%)		2 (3%)	
Stage 3	1 (2%)		1 (2%)	
Stage 4	1 (2%)		2 (3%)	
Questionable		1 (2%)		
Posthemorrhagic Hydrocephalus developed?				
No	61 (98%)	65 (98%)	64 (97%)	1.00
Yes	1 (2%)	1 (2%)	2 (3%)	

*The statistical test was based on a dichotomous response: present or absent.

-56-

Table 12
Serious Adverse Events Reported During Study Formula Phase

Event	Regimen			p-value
	Control	DHA	DHA+ARA	
Any Event	4 (6%)	3 (5%)	4 (6%)	0.93
Other Respiratory Conditions of Fetus and Newborn	2 (3%)	0	0	0.10
Other Infection Specific to the Perinatal Period	1 (2%)	0	0	0.32
Intraventricular Hemorrhage	0	0	1 (2%)	1.00
Other Specified Perinatal Disorders of Digestive System	0	1 (2%)	0	1.00
Convulsions in Newborn	1 (2%)	0	0	0.32
Feeding Problems in Newborn	0	1 (2%)	1 (2%)	1.00
Hernia	0	0	1 (2%)	1.00
Other	0	1 (2%)	1 (2%)	1.00

-57-

Table 13

Serious Adverse Events Reported During the Term Formula Phase

Event	Regimen				p-value
	Control	DHA	DHA + ARA	HM	
Any Event	7 (13%)	9 (15%)	9 (15%)	1 (1%)	0.002 C vs D 0.79 C vs D+A 0.79 D vs D+A 1.00 C vs HM 0.006 D vs HM 0.001 D+A vs HM 0.001
Infectious Colitis, Enteritis, and Gastroenteritis	0	0	1 (2%)	0	0.67
Croup	0	0	1 (2%)	0	0.67
Bronchopneumonia, Organism Unspecified	2 (4%)	3 (5%)	6 (10%)	0	0.013 C vs D 1.00 C vs D+A 0.27 D vs D+A 0.49 C vs HM 0.15 D vs HM 0.064 D+A vs HM 0.004
Asthma, Unspecified	1 (2%)	0	0	0	0.21
Esophageal Reflux	0	1 (2%)	2 (3%)	0	0.23
Dyspepsia and Other Stomach Function Disorder	0	0	0	1 (1%)	1.0
Other Respiratory Conditions of Fetus and Newborn	1 (2%)	1 (2%)	3 (5%)	0	0.11
Convulsions	1 (2%)	0	0	0	0.21
Sudden Infant Death Syndrome	1 (2%)	1 (2%)	0	0	0.34
Hernia	2 (4%)	2 (3%)	0	0	0.11
Other	0	3 (5%)	2 (3%)	0	0.063

- 58 -

Appendix 1
Listing of Weights Included in the Statistical Analyses

Gender	Regimen	Subject	Variable	Wgt1	Wgt2	Wgt3	Wgt4	Wgt5	Wgt6	Wgt7	Wgt8	Wgt9	Growth Rate g/day	Wgt_40	Wgt_48	Wgt_57	
Hale	Control	9698-0301	Weight (g) Age (Weeks pca)	1120 30.3	1240 31.3	1360 32.1	1590 33.1	1870 34.1					27.7				
Hale	Control	9698-0304	Weight (g) Age (Weeks pca)	1450 32.6	1630 33.4	1940 34.7	2180 35.4						36.1	3731 40.3	5752 48.3	6816 56.6	
Hale	Control	9699-0302	Height (g) Age (Weeks pca)	958.0 30.7	1108 31.7	1251 32.7	1378 33.7	1659 34.7					23.9	3064 39.9	4993 48.0	6553 57.9	
Hale	Control	9699-0306	Weight (g) Age (Weeks pca)	1185 31.0	1261 32.0	1437 33.0	1647 34.0	1933 35.0					26.9	3575 40.3	4936 48.3	6014 57.1	
Hale	Control	9699-0308	Weight (g) Age (Weeks pca)	1600 34.4	1840 35.4	2752 38.3							43.3	3688 40.3	5504 48.3	6922 57.3	
Hale	Control	9700-0301	Weight (g) Age (Weeks pca)	1810 32.1	1855 32.6	2075 33.4	2330 34.4	2595 35.4	3120 37.4				36.2	3745 40.1	5080 47.6	6610 56.7	
Hale	Control	9701-0303	Weight (g) Age (Weeks pca)	1181 32.4	1298 33.4	1496 34.4	1785 35.4	2012 36.3					31.5	3070 41.6	3895 48.6	4965 57.6	
Hale	Control	9701-0304	Weight (g) Age (Weeks pca)	1412 31.9	1566 32.9	1851 33.7	2117 34.7	2318 35.9					34.1	3070 39.9	5445 48.3	7135 56.9	
Hale	Control	9702-0302	Weight (g) Age (Weeks pca)	1480 31.0	1775 32.1	1566 33.0	2045 34.0	2240 34.6	2340 35.6	2570				33.8	3590 40.1	4840 48.6	6110 58.4
Hale	Control	9703-0302	Weight (g) Age (Weeks pca)	1785 33.3	2040 34.6	2375 35.6	2685 36.4	2955 37.4					41.7	3620 39.7	5850 48.6	7470 57.3	
Hale	Control	9703-0304	Weight (g) Age (Weeks pca)	1475 31.7	1705 33.0	1920 34.0	2190 34.9	2425 35.7					34.2	3170 40.1	5240 47.7	6970 57.1	
Hale	Control	9703-0308	Weight (g) Age (Weeks pca)	1140 31.7	1230 32.6	1445 33.7	1665 34.7	1945 35.7					28.9	2520 39.7	4010 48.4	5030 56.9	
Hale	Control	9704-0303	Weight (g) Age (Weeks pca)	975.0 32.3	1205 33.4	1450 34.4	1760 35.4	2045 36.3	2370 37.3	2685 38.3			24.4	2150 39.3	3700 48.3	4950 57.4	

* Four subjects had more than 9 weights used in growth rate calculation. A complete listing appears on the last page.

Appendix 1
Listing of Weights Included in the Statistical Analyses

Gender	Regimen	Subject	Variable	Wgt1	Wgt2	Wgt3	Wgt4	Wgt5	Wgt6	Wgt7	Wgt8	Wgt9	Growth Rate g/day	Wgt_40	Wgt_48	Wgt_57	
Hale	Control	9704-0305	Weight (g) Age (Weeks pca)	1315 30.9	1475 32.0	1640 33.0	1860 34.1						23.7				
Hale	Control	9705-0302	Weight (g) Age (Weeks pca)	1280 33.0	1389 34.0	1588 35.0	1786 36.0	2240 37.4					30.9	2540 39.6	4936 47.4	5646 56.4	
Hale	Control	9705-0304	Weight (g) Age (Weeks pca)	1270 31.3	1280 32.3	1570 33.3	1810 34.6						25.3	3291 39.7	5816 47.7	7490 56.7	
Hale	Control	9706-0302	Weight (g) Age (Weeks pca)	1645 35.7	1865 36.6	2130 37.7	2435 38.7						37.1	2800 40.1	4660 48.7	6170 56.7	
Hale	Control	9706-0303	Weight (g) Age (Weeks pca)	1875 33.7	1984 34.7	2135 35.6	2185 36.4	2465 37.3					22.2	3050 41.0	4550 48.6	6675 56.9	
Hale	Control	9706-0308	Weight (g) Age (Weeks pca)	1655 32.9	1734 33.1	2005 34.0	2495 35.4						46.9	3835 40.6	5155 48.0	6090 56.3	
Hale	Control	9707-0302	Weight (g) Age (Weeks pca)	1544 31.6	1820 32.9	2215 33.4	2450 35.4	2460 35.7					32.8	2930 40.1	3795 47.7	5185 56.6	
Hale	Control	9707-0303	Weight (g) Age (Weeks pca)	1415 33.1	1600 34.1	1850 35.1	2195 36.6	2310 37.1					32.7	2530 39.7	4235 47.7	6530 57.1	
Hale	Control	9707-0309	Weight (g) Age (Weeks pca)	1046 30.9	1442 32.7	1644 33.7	1910 34.9						30.7	2965 39.9	4465 48.0	4235 56.3	
Hale	Control	9708-0303	Weight (g) Age (Weeks pca)	1730 32.7	1960 33.7	2205 34.7	2520 35.7						37.4	3680 40.1	5470 48.1	7330 57.0	
Hale	Control	9709-0302	Weight (g) Age (Weeks pca)	1090 29.9	1440 31.7	1660 32.7	1910 33.7	2040 34.3					30.8	3845 39.9	5700 48.0	6775 56.7	
Hale	Control	9712-0301*	Weight (g) Age (Weeks pca)	1245 31.6	1221 31.7	1245 31.9	1291 32.0	1294 32.1	1330 32.3	1369 32.4	1402 32.6	1433 32.7	26.1				
Hale	Control	9712-0302	Weight (g) Age (Weeks pca)	1292 33.1	1345 34.1	1456 35.1	1670 36.1	1835 37.1	1985 38.1					21.0	2160 40.1	3300 47.7	3980 57.3

* Four subjects had more than 9 weights used in growth rate calculation. A complete listing appears on the last page.

-60-

Appendix 1
Listing of Weights Included in the Statistical Analyses

Gender	Regimen	Subject	Variable	Wgt1	Wgt2	Wgt3	Wgt4	Wgt5	Wgt6	Wgt7	Wgt8	Wgt9	Growth Rate g/day	Wgt_40	Wgt_48	Wgt_57	
Male	Control	9743-0301	Weight (g)	1520	1570	1670	1720						10.0	2260	4535		
Male	Control	9746-0301	Weight (g) Age (weeks pca)	34.1	35.0	36.0	37.1							41.0	50.0		
Male	DIA	9698-0302	Weight (g) Age (weeks pca)	2065	2465	2760	3085	3085	40.6				48.9	3085	4795	6695	
Male	DIA	9698-0306	Weight (g) Age (weeks pca)	37.6	38.9	39.7	40.6							47.6	57.6		
Male	DIA	9699-0301	Weight (g) Age (weeks pca)	1640	1860	3170							47.5	3170	5206	7036	
Male	DIA	9699-0303	Weight (g) Age (weeks pca)	35.1	36.1	39.9								39.9	47.9	57.1	
Male	DIA	9699-0307	Weight (g) Age (weeks pca)	1620	1830	2090	2575						28.3	2575	4336	6022	
Male	DIA	9700-0303	Weight (g) Age (weeks pca)	35.1	36.3	37.3	40.0							40.0	48.0	57.0	
Male	DIA	9701-0301	Weight (g) Age (weeks pca)	1018	1207	1360	1617						27.9	3121	5192	6752	
Male	DIA	9701-0305	Weight (g) Age (weeks pca)	31.3	32.3	33.3	34.3							39.9	48.0	57.9	
Male	DIA	9703-0303	Weight (g) Age (weeks pca)	1258	1435	1631	1882	2724					48.3	2724	4341	5674	
Male	DIA	9703-0306	Weight (g) Age (weeks pca)	32.4	33.4	34.4	35.4	36.4						40.1	48.1	57.0	
Male	DIA	9703-0307	Weight (g) Age (weeks pca)	34.7	35.7	36.7	37.7							22.5	1986	3206	4511
Male	DIA	9700-0303	Weight (g) Age (weeks pca)	1830	1980	2450	3065								40.0	48.0	57.0
Male	DIA	9701-0301	Weight (g) Age (weeks pca)	33.9	34.4	35.9	37.7										
Male	DIA	9701-0305	Weight (g) Age (weeks pca)	1098	1234	1365	1689	1902	2019	2104	2276	2288	20.4	2805	3405	4660	
Male	DIA	9703-0303	Weight (g) Age (weeks pca)	29.6	30.6	31.6	33.4	34.6	35.6	36.4	37.4	38.6		45.4	3585	5420	7035
Male	DIA	9703-0306	Weight (g) Age (weeks pca)	31.7	33.1	33.7	34.7	35.7							39.6	47.4	56.7
Male	DIA	9703-0307	Weight (g) Age (weeks pca)	32.7	33.7	34.1	35.1	36.0	37.1								
Male	DIA	9703-0303	Weight (g) Age (weeks pca)	1775	2030	2285	2595	2780									
Male	DIA	9703-0306	Weight (g) Age (weeks pca)	33.4	34.0	35.0											
Male	DIA	9703-0307	Weight (g) Age (weeks pca)	32.7	33.7	34.9	36.0										

* Four subjects had more than 9 weights used in growth rate calculation. A complete listing appears on the last page.

-61-

Appendix 1
Listing of Weights Included in the Statistical Analyses

Gender	Regimen	Subject	Variable	Wgt1	Wgt2	Wgt3	Wgt4	Wgt5	Wgt6	Wgt7	Wgt8	Wgt9	Growth Rate g/day	Wgt_40	Wgt_48	Wgt_57	
Hale	DHA	9704-0304	Weight (g) Age (Weeks pca)	1380 32.1	1570 33.1	1730 34.1	1960 35.0	2140 35.9					29.3	2880 40.3	3900 48.3	4300 57.3	
Hale	DIA	9704-0306	Weight (g) Age (Weeks pca)	1320 30.7	1370 31.7	1550 32.7	1760 33.7	2020 34.7	2170 35.9					25.6	3750 48.0	4800 57.0	
Hale	DIA	9705-0303	Weight (g) Age (Weeks pca)	1380 33.0	1446 34.0	1616 35.0	1863 36.0	2330 37.4					30.8	2370 39.6	4170 47.4	5787 56.4	
Hale	DIA	9705-0305	Weight (g) Age (Weeks pca)	1490 31.1	1770 32.1	1980 33.1	2240 34.0						36.7	3291 39.6			
Hale	DIA	9706-0304	Weight (g) Age (Weeks pca)	1490 33.0	1655 33.7	1915 34.7	2260 36.0						36.8	3335 40.0	5265 48.1	6900 57.3	
Hale	DIA	9706-0306	Weight (g) Age (Weeks pca)	1604 34.4	1908 35.4	2160 36.3							42.8	3310 41.4	4205 47.6	5600 56.9	
Hale	DIA	9707-0001	Weight (g) Age (Weeks pca)	1305 31.0	1429 32.0								17.7				
Hale	DIA	9707-0304	Weight (g) Age (Weeks pca)	1555 32.0	1740 33.0	1990 34.0	2400 35.4	2570 36.0					36.9	3280 39.9	5115 48.0	6755 57.6	
Hale	DIA	9707-0306	Weight (g) Age (Weeks pca)	1728 36.1	2040 37.3	2260 38.1	3050 40.6	3050 40.6					43.2	3050 40.6	5100 48.6	7150 57.6	
Hale	DIA	9707-0307*	Weight (g) Age (Weeks pca)	1649 32.4	1675 32.6	1699 32.7	1732 32.9	1778 33.0	1811 33.1	1882 33.3	1938 33.4	1938 33.6	39.6	36.7	3004 39.3	4420 47.3	6090 57.7
Hale	DIA	9707-1308	Weight (g) Age (Weeks pca)	1780 34.4	2045 35.7	3004 39.3	3004 39.3	3004 39.3						35.8	2850 39.3	4375 47.3	5930 57.7
Hale	DIA	9707-2308	Weight (g) Age (Weeks pca)	1651 34.4	1923 35.7	2850 39.3	2850 39.3							39.2	3873 42.9	6256 57.3	

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-62-

Appendix 1
Listing of Weights Included in the Statistical Analyses

Gender	Regimen	Subject	Variable	Wgt1	Wgt2	Wgt3	Wgt4	Wgt5	Wgt6	Wgt7	Wgt8	Wgt9	Growth Rate g/day	Wgt_40	Wgt_48	Wgt_57
Male	DHA	9709-0301	Weight (g) Age (Weeks pca)	1490 32.4	1740 33.4	2000 34.4	2400 35.4	2600 36.7					44.4	3150 39.4	5080 47.4	6750 56.4
Male	DIA	9709-0304	Weight (g) Age (Weeks pca)	1470 34.4	1520 35.4								7.1			
Male	DIA	9712-0304	Weight (g) Age (Weeks pca)	1545 33.0	1800 34.0	1985 35.0	2160 36.0	2550 37.6					30.5	3160 40.3	5200 48.1	7300 57.1
Male	DIA	9712-0306	Weight (g) Age (Weeks pca)	1240 31.5	1435 32.5	1695 33.5	1945 34.5						33.9	3040 39.6	4680 48.6	5860 57.6
Male	DIA	9743-0303	Weight (g) Age (Weeks pca)	1700 32.9	1810 33.9	2100 34.9	2300 35.7						31.1	3100 40.6	5500 48.6	
Male	DIA	9743-0304	Weight (g) Age (Weeks pca)	1530 32.3	1880 34.0	2160 35.0	2375 36.0	2440 36.4					32.2	3628 38.1	5840 50.6	
Male	DHA+ARA	9698-0305	Weight (g) Age (Weeks pca)	1120 30.7	1340 32.6	1550 33.6							20.9	2440 37.4	5525 47.6	6646 56.6
Male	DIA+ARA	9698-0308	Weight (g) Age (Weeks pca)	1410 31.1	1690 32.4	1870 33.3	2120 34.3						32.0	3553 40.3	6007 47.6	7937 57.3
Male	DIA+ARA	9699-0304	Weight (g) Age (Weeks pca)	1499 36.1	1689 37.1	1950 38.1	2355 40.3						29.8	2355 40.3	3404 48.0	4993 57.1
Male	DIA+ARA	9699-0305	Weight (g) Age (Weeks pca)	1056 32.0	1134 33.0	1290 34.0	1490 35.7						17.2	2610 40.6	4256 48.7	5050 57.6
Male	DIA+ARA	9700-0302	Weight (g) Age (Weeks pca)	1635 33.9	1880 34.7	2235 35.9	2570 36.9	2735 37.9					40.7	3255 39.7	5540 47.7	7380 56.7
Male	DIA+ARA	9701-0302	Weight (g) Age (Weeks pca)	1442 33.6	1686 34.6	2045 35.6	2835 37.7						48.9	3240 39.7	5055 46.7	6600 56.7
Male	DIA+ARA	9701-0306	Weight (g) Age (Weeks pca)	1587 32.3	2037 33.4	2245 34.4	2460 35.3	2756 36.3	3072 37.3	3228 37.7			41.4	3960 42.3	5200 48.4	

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-63-

Appendix 1

Listing of Weights Included in the Statistical Analyses

Gender	Regimen	Subject	Variable	Wgt1	Wgt2	Wgt3	Wgt4	Wgt5	Wgt6	Wgt7	Wgt8	Wgt9	Growth Rate g/day	Wgt_40	Wgt_48	Wgt_57
Hale	DHA+ARA	9701-0307	Weight (g) Age (weeks pca)	1397 33.3	1710 34.3	1919 35.1	2032 36.4						42.5	3445	5930	7475
Hale	DHA+ARA	9702-0301	Weight (g) Age (weeks pca)	1670 32.0	1865 33.0	2160 34.0	2660 36.0						40.6	40.6	48.6	57.4
Hale	DHA+ARA	9702-0303	Weight (g) Age (weeks pca)	1650 32.9	1905 33.9	2660 36.4							40.7	3500	5160	6520
Hale	DHA+ARA	9703-0301	Weight (g) Age (weeks pca)	1255 29.4	1460 30.4	1745 31.3	2055 32.3	2415 33.4					42.3	4350	6020	6720
Hale	DHA+ARA	9703-0305	Weight (g) Age (weeks pca)	1440 32.0	1635 33.0	1830 34.0	2115 35.0	2390 36.1	2590 36.9				34.1	3170	4330	5630
Hale	DHA+ARA	9704-0301	Weight (g) Age (weeks pca)	1110 30.6	1270 31.6	1490 32.4	1740 33.4	2050 34.4					35.1	3220	5460	7050
Hale	DHA+ARA	9704-0302	Weight (g) Age (weeks pca)	1080 32.0	1230 33.0	1370 34.0	1520 34.9	1680 36.0	1840 36.9				22.2	2570	6540	8050
Hale	DHA+ARA	9705-0301	Weight (g) Age (weeks pca)	1300 32.7	1440 33.7	1620 34.7	1870 35.7						27.0	2979	4400	5873
Hale	DHA+ARA	9705-0306	Weight (g) Age (weeks pca)	1320 31.4	1490 32.4	1700 33.4	2020 34.4	2300 35.9					32.7	3631	5447	6809
Hale	DHA+ARA	9705-0307	Weight (g) Age (weeks pca)	1480 34.4	1650 35.4	1810 36.1	2240 37.4						36.4	3007	5589	6596
Hale	DHA+ARA	9706-0305	Weight (g) Age (weeks pca)	1330 33.9	1455 34.4	1660 35.4	1930 36.6						31.4	2695	4820	6225
Hale	DHA+ARA	9706-0307	Weight (g) Age (weeks pca)	1355 31.9	1585 33.0	1825 33.9	2270 35.1						40.0	3585	5955	6925
Hale	DHA+ARA	9706-0309	Weight (g) Age (weeks pca)	1620 34.1	1910 35.3	2150 36.0							40.3	3460	5255	5775

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-64-

Appendix 1

Listing of Weights Included in the Statistical Analyses

Gender	Regimen	Subject	Variable	Wgt1	Wgt2	Wgt3	Wgt4	Wgt5	Wgt6	Wgt7	Wgt8	Wgt9	Growth Rate g/day	Wgt_40	Wgt_48	Wgt_57	
Male	DHA+ARA	9707-0301	Weight (g) Age (weeks pca)	1553 32.6	1980 34.3	2280 35.3	2720 36.6						41.5 40.1	3395 4950	47.9 56.9	6285	
Male	DHA+ARA	9707-0305	Weight (g) Age (weeks pca)	1755 33.9	1990 34.7	2245 35.7	2505 36.7	2770 37.7					37.4				
Male	DHA+ARA	9707-0310	Weight (g) Age (weeks pca)	1620 32.7	1828 33.7	2140 34.7	2195 37.9						44.8 39.7	3585 5170	47.9 56.3	6725	
Male	DHA+ARA	9708-0301	Weight (g) Age (weeks pca)	1640 32.7	1880 33.7	2200 34.7	2420 35.7						38.0 40.1	3730 4835	47.9 57.0	6185	
Male	DHA+ARA	9708-0306	Weight (g) Age (weeks pca)	1680 34.6	2180 35.9								55.6				
Male	DHA+ARA	9709-0303	Weight (g) Age (weeks pca)	1470 32.6	1810 33.6								48.6				
Male	DHA+ARA	9709-0305	Weight (g) Age (weeks pca)	1410 34.4	1655 35.4	1900 36.4	2160 37.4						35.6 39.7	2630 47.7	4570 57.1	5520	
Male	DHA+ARA	9712-0303	Weight (g) Age (weeks pca)	1180 31.4	1210 32.3	1450 33.4	1590 34.4						20.9 40.4	2520 47.4			
Male	DHA+ARA	9712-0305	Weight (g) Age (weeks pca)	1325 31.5	1505 32.5	1785 33.5	2010 34.5	2300 35.6					34.1 39.6	3030 48.6	4350 57.6	5010	
Male	DHA+ARA	9723-0301	Weight (g) Age (weeks pca)	1630 33.9	1728 34.9	1961 35.9	2214 36.9						28.4 40.3	3104 40.3			
Male	HM	9698-0601												3518 40.0	5497 48.3	6582 56.9	
Male	HM	9698-0602												3177 40.0	5220 48.1	6355 57.0	
Male	HM	9698-0603												3858 40.0	5447 48.0	6454 57.0	

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-65-

Appendix 1
Listing of Weights Included in the Statistical Analyses

Gender	Regimen	Subject	Variable	Wgt1	Wgt2	Wgt3	Wgt4	Wgt5	Wgt6	Wgt7	Wgt8	Wgt9	Growth Rate g/day	Wgt_40	Wgt_48	Wgt_57
Male	HM	9698-0604											4355	5092	6383	
Male	HM	9698-0605											40.0	48.0	57.0	
Male	HM	9699-0501											3433	4979	6426	
Male	HM	9699-0502											40.0	48.1	57.1	
Male	HM	9701-0601											3915	6639	7773	
Male	HM	9701-0602											40.0	48.3	57.4	
Male	HM	9701-0603											3802	5787	7178	
Male	HM	9701-0604											40.0	48.4	57.4	
Male	HM	9701-0605											3317	5555	7070	
Male	HM	9701-0606											40.0	47.9	56.4	
Male	HM	9702-0601											3487	5833	8070	
Male	HM	9702-0602											40.0	47.3	58.3	
Male	HM	9702-0603											3232	4940	5855	
Male	HM	9702-0604											40.0	47.4	56.4	
Male	HM	9702-0605											3600	5215	6285	
Male	HM	9702-0606											40.0	47.9	56.9	
Male	HM	9702-0607											3402	5575	7210	
Male	HM	9702-0608											40.0	47.6	57.6	
Male	HM	9702-0609											3090	4485	5445	
Male	HM	9702-0610											40.0	47.7	56.7	
Male	HM	9703-0502											3480	5780	6530	
Male	HM	9703-0503											40.0	48.6	56.6	
Male	HM	9703-0504											3165	5060	6660	
Male	HM	9703-0505											40.0	48.3	57.1	
Male	HM	9703-0506											2670	5420	7220	
Male	HM	9703-0507											40.0	48.3	57.1	

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-66-

Appendix 1
Listing of Weights Included in the Statistical Analyses

Gender	Regimen	Subject	Variable	Wgt1	Wgt2	Wgt3	Wgt4	Wgt5	Wgt6	Wgt7	Wgt8	Wgt9	Growth Rate g/day	Wgt_40	Wgt_48	Wgt_57
Male	HM	9703-0503												4100	6740	8330
Male	HM	9703-0504												40.0	47.4	56.4
Male	HM	9704-0502												3635	6000	7910
Male	HM	9704-0503												40.0	48.1	57.1
Male	HM	9705-0601												3285	5220	6560
Male	HM	9705-0602												40.0	48.1	56.6
Male	HM	9706-0601												3400	5200	6725
Male	HM	9706-0602												3200	5617	6752
Male	HM	9706-0603												40.0	48.3	57.3
Male	HM	9706-0604												3860	6227	
Male	HM	9706-0605												40.0	48.0	
Male	HM	9707-0601												3152	5105	6545
Male	HM	9707-0602												40.0	49.0	57.0
Male	HM	9708-0601												3557	5175	7315
Male	HM	9708-0602												40.0	47.4	57.7
Male	HM	9708-0603												3192	5070	6970
Male	HM	9708-0604												40.0	47.9	56.7
Male	HM	9708-0605												3461	4225	5525
Male	HM	9708-0606												40.0	48.0	57.1
Male	HM	9708-0607												3870	6220	7660
Male	HM	9708-0608												40.0	48.1	56.4
Male	HM	9708-0609												4315	5975	6720
Male	HM	9708-0610												40.0	48.3	56.6
Male	HM	9708-0611												3263	4730	5825
Male	HM	9708-0612												40.0	48.1	57.0

* four subjects had more than 9 weights used in growth rate calculation. A complete listing appears on the last page.

-67-

Appendix 1

Listing of Weights Included in the Statistical Analyses

Gender	Regimen	Subject	Variable	Wgt1	Wgt2	Wgt3	Wgt4	Wgt5	Wgt6	Wgt7	Wgt8	Wgt9	Growth Rate g/day	Wgt_40	Wgt_48	Wgt_57
Hale	IH	9707-0602											3206	4515	6220	
Hale	IH	9707-0603											40.0	48.1	57.7	
Hale	IH	9707-0604											4256	6930	8810	
Hale	IH	9707-0605											40.0	48.0	57.0	
Hale	IH	9707-0606											3619	5660	6130	
Hale	IH	9707-0607											40.0	48.0	56.7	
Hale	IH	9707-0608											3433			
Hale	IH	9707-0609											40.0			
Hale	IH	9708-0601											3603	5825		
Hale	IH	9708-0602											40.0	48.4		
Hale	IH	9708-0603											3569	5410	6870	
Hale	IH	9708-0604											40.0	47.9	56.9	
Hale	IH	9708-0605											3348	5135	6370	
Hale	IH	9708-0606											40.0	48.0	57.0	
Hale	IH	9708-0607											3348			
Hale	IH	9708-0608											40.0			
Hale	IH	9708-0609											3064	5220	6595	
Hale	IH	9708-0610											40.0	47.6	56.4	
Hale	IH	9708-0611											4085			
Hale	IH	9708-0612											40.0			
Hale	IH	9708-0613											3319	5135	6327	
Hale	IH	9708-0614											40.0	48.4	57.1	
Hale	IH	9708-0615											3291			
Hale	IH	9708-0616											40.0			

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-68-

Appendix 1
Listing of Weights Included in the Statistical Analyses

Gender	Regimen	Subject	Variable	Wgt1	Wgt2	Wgt3	Wgt4	Wgt5	Wgt6	Wgt7	Wgt8	Wgt9	Growth Rate g/day	Wgt_4.0	Wgt_4.8	Wgt_5.7	
Hale	HM	9708-0606												4020	4645	5405	
Hale	IIM	9708-0607												40.0	48.4	57.1	
Hale	IIM	9709-0505												3333	4043	5180	
Female	Control	9698-0003*	Weight (g) Age (weeks pca)	1020	1050	1070	1080	1080	1080	1080	1080	1070	5.6				
Female	Control	9699-0001	Weight (g) Age (weeks pca)	31.1	31.3	31.4	31.6	31.7	31.9	32.0	32.1			24.1	2610	4369	5220
Female	Control	9699-0003	Weight (g) Age (weeks pca)	1464	1672	1862	2000	2145						39.7	47.9	56.9	
Female	Control	9699-0003	Weight (g) Age (weeks pca)	32.7	33.7	34.7	35.7	36.7						37.3	2780	4596	5816
Female	Control	9701-0003	Weight (g) Age (weeks pca)	1473	1629	1860	2497							40.0	48.0	57.0	
Female	Control	9701-0001	Weight (g) Age (weeks pca)	34.0	35.0	36.0	38.0							29.1	2675	4165	5200
Female	Control	9701-0005	Weight (g) Age (weeks pca)	34.6	1480	1633	1903	1975	2292					40.6	48.6	55.6	
Female	Control	9701-0008	Weight (g) Age (weeks pca)	30.7	1174	1366	1555	1745	1976					28.3	3175	5140	6280
Female	Control	9701-0011	Weight (g) Age (weeks pca)	30.6	1391	1569	1898	2198	2406					41.1	2980	4425	5815
Female	Control	9702-0002	Weight (g) Age (weeks pca)	34.3	1222	1371	1570	1750	1995	2390				40.4	47.4	56.4	
Female	Control	9702-0004	Weight (g) Age (weeks pca)	31.7	31.7	32.7	34.1	35.1	36.0	37.1				36.6	2870	4420	5505
Female	Control	9702-0010	Weight (g) Age (weeks pca)	34.0	1775	1454	1555	1840	2530					31.6	3600	5160	6900
				35.0	2065	31.0	31.9	33.1	36.0					42.2	3060	4820	6690
					36.0									39.9	48.3	57.6	

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Appendix 1
Listing of Weights Included in the Statistical Analyses

Gender	Regimen	Subject	Variable	Wgt1	Wgt2	Wgt3	Wgt4	Wgt5	Wgt6	Wgt7	Wgt8	Wgt9	Growth Rate g/day	Wgt_40	Wgt_48	Wgt_57
Female	Control	9703-0002	Weight (g) Age (Weeks pca)	1170	1250	1390	1570	1825	2130				26.4	3210	4750	
Female	Control	9703-0005	Weight (g) Age (Weeks pca)	29.1	30.4	31.3	32.4	33.4	34.3				39.6	39.6	47.4	
Female	Control	9703-0008	Weight (g) Age (Weeks pca)	1420	1590	1765	1900	2220				29.5	2610	4330	5640	
Female	Control	9703-0004	Weight (g) Age (Weeks pca)	31.4	32.3	31.3	33.9	35.3				37.3	46.0	55.0		
Female	Control	9706-0003	Weight (g) Age (Weeks pca)	1495	1715	2095	2445	2685				48.3	3360	4780	6410	
Female	Control	9706-0005	Weight (g) Age (Weeks pca)	33.0	34.0	35.0	36.0	36.6				40.1	47.7	56.1		
Female	Control	9706-0010	Weight (g) Age (Weeks pca)	1120	1290	1490	1660				28.3	2722	4085	5646		
Female	Control	9706-0013	Weight (g) Age (Weeks pca)	1515	1673	1965	2330				37.9	39.7	46.6	55.0		
Female	Control	9707-0003	Weight (g) Age (Weeks pca)	35.1	36.3	37.1	38.3									
Female	Control	9707-0006	Weight (g) Age (Weeks pca)	1485	1610	1805	2150				31.7	2740	4165	5305		
Female	Control	9707-0009	Weight (g) Age (Weeks pca)	33.0	33.7	34.7	36.0				40.0	48.1	57.3			
Female	Control	9707-0016	Weight (g) Age (Weeks pca)	1525	1620	1960					31.6	3640	5495	7225		
Female	Control	9707-0013	Weight (g) Age (Weeks pca)	32.3	32.9	34.3					40.3	47.6	53.4			
Female	Control	9707-0006	Weight (g) Age (Weeks pca)	1905	2185						56.0	3655	5390	6535		
Female	Control	9707-0011	Weight (g) Age (Weeks pca)	34.3	35.0						40.0	48.4	56.7			
Female	Control	9707-0014	Weight (g) Age (Weeks pca)	1185	1270	1585	1810				31.1	2680	3800			
Female	Control	9707-0012	Weight (g) Age (Weeks pca)	31.6	32.4	33.6	34.6				40.1	48.4				
Female	Control	9707-0015	Weight (g) Age (Weeks pca)	32.0	33.1	33.9					32.6	3320	4535	5297		
Female	Control	9707-0003	Weight (g) Age (Weeks pca)	32.0	32.6	33.6	35.3	36.4	38.3		30.2	3110	4125	4995		
Female	Control	9707-0006	Weight (g) Age (Weeks pca)	36.6	40.0	40.0					40.1	48.1	57.1			
Female	Control	9707-1006	Weight (g) Age (Weeks pca)	1815	3330	3330	40.0	40.0			41.2	3430	5385	7250		
Female	Control			34.6							39.9	3330	5490	6920		
											40.0	48.9	57.3			

* Four subjects had more than 9 weights used in growth rate calculation. A complete listing appears on the last page.

-70-

Appendix 1
Listing of Weights Included in the Statistical Analyses

Gender	Regimen	Subject	Variable	Wgt1	Wgt2	Wgt3	Wgt4	Wgt5	Wgt6	Wgt7	Wgt8	Wgt9	Growth Rate g/day	Wgt_40	Wgt_48	Wgt_57
Female	Control	9708-0001	Weight (g) Age (Weeks pca)	1410	1600	1850	2050						27.2	2910	40.6	4734
Female	Control	9708-0003	Weight (g) Age (Weeks pca)	960.0	970.0	30.0	31.0	35.4	36.9					4.3		48.4
Female	Control	9708-0008	Weight (g) Age (Weeks pca)	1380	1605	1860	2180									
Female	Control	9709-0002	Weight (g) Age (Weeks pca)	1980	2225	2400										
Female	Control	9709-0005	Weight (g) Age (Weeks pca)	32.7	33.7	34.7										
Female	Control	9712-0005	Weight (g) Age (Weeks pca)	1175	1425	1665	1945	2200								
Female	Control	9712-0006	Weight (g) Age (Weeks pca)	31.9	33.3	34.6	35.6	36.3								
Female	Control	9743-0003	Weight (g) Age (Weeks pca)	972.0	1145	1290	1490	1695								
Female	Control	9746-0001	Weight (g) Age (Weeks pca)	29.1	30.1	31.1	32.1	33.1								
Female	DIA	9698-0004	Weight (g) Age (Weeks pca)	1203	1358	1585	1790									
Female	DIA	9698-0006	Weight (g) Age (Weeks pca)	31.9	32.9	33.9	34.9									
Female	DIA	9698-0009	Weight (g) Age (Weeks pca)	1300	1520	1740	1890									
Female	DIA	9698-0307	Weight (g) Age (Weeks pca)	31.6	33.4	34.1	35.1									
Female	DIA	9698-0006	Weight (g) Age (Weeks pca)	1420	1740	2075	2320	2625								
Female	DIA	9698-0004	Weight (g) Age (Weeks pca)	32.6	33.6	34.6	35.6	36.6								
Female	DIA	9698-0006	Weight (g) Age (Weeks pca)	1410	1650	1890	2140									
Female	DIA	9698-0009	Weight (g) Age (Weeks pca)	30.1	31.1	32.1	33.1									
Female	DIA	9698-0307	Weight (g) Age (Weeks pca)	1110	1240	1420	1720									
Female	DIA	9698-0006	Weight (g) Age (Weeks pca)	30.7	31.7	32.7	33.7									
Female	DIA	9698-0009	Weight (g) Age (Weeks pca)	1205	1310	1520	1630	2020								
Female	DIA	9698-0307	Weight (g) Age (Weeks pca)	30.3	31.4	32.4	33.1	34.9								

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Appendix 1
Listing of Weights Included in the Statistical Analyses

Gender	Regimen	Subject	Variable	Wgt1	Wgt2	Wgt3	Wgt4	Wgt5	Wgt6	Wgt7	Wgt8	Wgt9	Growth Rate g/day	Wgt_48	Wgt_57
Female	DIA	9699-0002	Weight (g) Age (weeks pca)	1313	1477	1669	1929	2380					36.9	3177	5787
Female	DIA	9700-0001	Weight (g) Age (weeks pca)	32.9	33.9	34.9	35.9	36.9					39.7	47.7	56.7
Female	DIA	9701-0001	Weight (g) Age (weeks pca)	1580	1820	2050	2295	2500					34.5	3210	5110
Female	DIA	9701-0004	Weight (g) Age (weeks pca)	32.4	33.4	34.3	35.3	36.3					40.1	48.1	57.1
Female	DIA	9701-0012	Weight (g) Age (weeks pca)	1108	1261	1441	1671	1897					34.2	2910	4325
Female	DIA	9701-0014	Weight (g) Age (weeks pca)	30.7	31.7	32.7	33.7	34.7					39.6	48.0	57.0
Female	DIA	9702-0001	Weight (g) Age (weeks pca)	1674	1928	2151	2311	2685	2685				28.4	3020	4855
Female	DIA	9702-0006	Weight (g) Age (weeks pca)	34.9	35.9	36.9	37.6	39.6	39.6				39.7	48.4	56.4
Female	DIA	9702-0007	Weight (g) Age (weeks pca)	1422	1631	1858	2455						30.1	2685	
Female	DIA	9702-0008	Weight (g) Age (weeks pca)	33.9	34.9	35.9	37.9						37.2	2970	4605
Female	DIA	9703-0003	Weight (g) Age (weeks pca)	1605	1930	3540	3540						39.9	47.7	56.9
Female	DIA	9703-0004	Weight (g) Age (weeks pca)	34.1	35.1	39.6	39.6						35.8	3850	5610
Female	DIA	9703-0009	Weight (g) Age (weeks pca)	1285	1459	1780	1965	2035					40.0	49.6	57.0
Female	DIA		Age (weeks)	31.1	32.1	33.6	34.4	34.9					27.3	2650	4450
Female	DIA		Age (weeks)	32.6	33.3	34.3	35.3	37.0					39.6	48.4	56.4

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-72-

Appendix 1
Listing of Weights Included in the Statistical Analyses

Gender	Regimen	Subject	Variable	Wgt1	Wgt2	Wgt3	Wgt4	Wgt5	Wgt6	Wgt7	Wgt8	Wgt9	Growth Rate g/day	Wgt_40	Wgt_48	Wgt_57
Female	DHA	9704-0004	Weight (g) Age (Weeks pca)	1440 33.6	1670 34.6	1740 35.0							30.5	3100	5830	8630
Female	DHA	9704-0005	Weight (g) Age (Weeks pca)	1050 29.7	1310 30.9	1490 31.7	1700 32.7	1890 33.7					30.0	3360	4860	6100
Female	DIA	9705-0001	Weight (g) Age (Weeks pca)	1220 32.7	1370 33.6	1590 34.7	1880 35.7	2098 36.7					31.9	3092	4795	5986
Female	DIA	9706-0006	Weight (g) Age (Weeks pca)	1270 33.0	1405 33.7	1630 34.7	1930 36.0						31.7	2705	4145	5320
Female	DIA	9706-0008	Weight (g) Age (Weeks pca)	990.0 33.4	1188 34.6	1345 35.7	1485 36.4						23.0	2120	39.9	
Female	DIA	9706-0012	Weight (g) Age (Weeks pca)	1610 31.6	1830 32.4	2130 33.6	2280 34.6						32.5	3530	4790	
Female	DIA	9706-0014	Weight (g) Age (Weeks pca)	1080 31.3	1170 32.6	1395 33.4	1560 34.4	1804 35.3					26.2	3295	5600	7675
Female	DIA	9707-0004	Weight (g) Age (Weeks pca)	1635 34.0	1771 35.0	2850 36.7							38.1	40.0	48.0	58.0
Female	DIA	9707-0308	Weight (g) Age (Weeks pca)	2005 34.4	3440 39.3	3440 39.3							42.2	3440	4800	6360
Female	DIA	9708-0004	Weight (g) Age (Weeks pca)	1460 32.6	1665 33.6	1955 34.6	2280 35.6	2485 36.6					38.1	3045	4595	5765
Female	DIA	9708-0006	Weight (g) Age (Weeks pca)	1485 33.7	1775 34.7	2110 35.7	2380 37.0						39.5	3010	4620	6530
Female	DIA	9709-0001	Weight (g) Age (Weeks pca)	1250 29.6	1490 31.0	1755 32.0	1970 33.0	2250 34.0	2520 35.0				33.8	3500	40.1	57.0
Female	DIA	9709-0003	Weight (g) Age (Weeks pca)	1540 34.4	1725 35.4	2015 36.4	2155 37.4						30.5	2580	4080	5420
														40.3	47.7	57.1

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-73-

Appendix 1
Listing of Weights Included in the Statistical Analyses

Gender	Regimen	Subject	Variable	Wgt1	Wgt2	Wgt3	Wgt4	Wgt5	Wgt6	Wgt7	Wgt8	Wgt9	Growth Rate g/day	Wgt_48	Wgt_57		
Female	DIA	9712-0001	Weight (g) Age (Weeks pca)	987.0 30.0	1120 31.0	1270 32.0	1470 33.0	1685 34.0					24.9	294.0 40.1	3950 48.1	5250 57.1	
Female	DIA	9712-0002	Weight (g) Age (Weeks pca)	1060 32.7	1230 33.7	1440 34.7	1650 35.7						26.4				
Female	DIA	9712-0007	Weight (g) Age (Weeks pca)	1092 32.7	1230 33.7	1440 34.7	1650 35.7						27.3	2425 39.7	4250 47.9	5340 56.9	
Female	DIA	9743-0001	Weight (g) Age (Weeks pca)	1000 32.1	1170 33.1	1470 34.4	1800 35.7	1930 36.1					33.5		414.0 48.3	5400 57.3	
Female	DIA	9743-0002	Weight (g) Age (Weeks pca)	1380 32.1	1570 33.3	1845 34.1	1975 35.1						29.7		4540 48.4	5160 57.4	
Female	DIA+ARA	9698-0001	Weight (g) Age (Weeks pca)	1550 31.6	1690 32.6	2000 33.6	2380 34.9						37.1	3530 40.0	5348 47.7	6582 56.7	
Female	DIA+ARA	9698-0002	Weight (g) Age (Weeks pca)	1580 32.6	1870 33.7	2130 34.6	2260 35.7						31.8		3241 40.7		
Female	DIA+ARA	9699-0004	Weight (g) Age (Weeks pca)	985.0 31.0	1122 32.0	1283 33.0	1536 34.0	1788 35.0					28.9	3177 41.3	5107 48.3	6979 57.3	
Female	DIA+ARA	9699-0005	Weight (g) Age (Weeks pca)	1330 31.9	1542 32.9	1688 33.9	2000 34.9	2330 35.9					35.1	4029 40.3	4752 48.1	8341 57.0	
Female	DIA+ARA	9700-0002	Weight (g) Age (Weeks pca)	1315 30.3	1525 31.3	1885 32.3	2035 33.3	2220 34.1	2480 35.6					31.9	3340 40.3	4930 48.1	6420 57.1
Female	DIA+ARA	9701-0002	Weight (g) Age (Weeks pca)	1398 33.4	1609 34.4	1887 35.4	2210 36.4	2420 37.4					37.8	2930 39.4	5115 48.4	6525 56.4	
Female	DIA+ARA	9701-0006	Weight (g) Age (Weeks pca)	1720 32.3	1859 33.3	2113 34.3	2456 35.3	2728 36.1					38.3	3600 40.3	5045 48.0	6270 57.3	
Female	DIA+ARA	9701-0007	Weight (g) Age (Weeks pca)	1649 33.7	1427 34.9	1590 35.7	1982 36.7	2227 37.7					29.8	2680 39.9	4935 47.9	6955 56.9	

* Four subjects had more than 9 weights used in growth rate calculation. A complete listing appears on the last page.

-74-

Appendix 1
Listing of Weights Included in the Statistical Analyses

Gender	Regimen	Subject	Variable	Wgt1	Wgt2	Wgt3	Wgt4	Wgt5	Wgt6	Wgt7	Wgt8	Wgt9	Growth Rate g/day	Wgt_40	Wgt_48	Wgt_57
Female	DHA+ARA	9701-0010	Weight (g) Age (weeks pca)	1488 32.3	1703 33.4	1978 35.3	2234 36.1	2433 36.1	2759 37.7				34.6	3500 41.1	5545 48.4	
Female	DHA+ARA	9701-0013	Weight (g) Age (weeks pca)	1841 33.0	2019 33.7								35.6	4545 48.7	5550 57.4	
Female	DHA+ARA	9702-0003	Weight (g) Age (weeks pca)	1293 30.1	1488 31.1	1820 32.1	2155 33.4	2400 34.1					39.9	4190 40.0	6220 48.4	7500 56.9
Female	DHA+ARA	9702-0005	Weight (g) Age (weeks pca)	1895 34.0	2060 35.0	2300 36.0	2525 37.0	2710 38.0					29.9	3025 40.0	4300 47.4	5340 56.4
Female	DHA+ARA	9702-0009	Weight (g) Age (weeks pca)	1725 34.0	2000 35.0	2230 36.0	2595 37.0	2655 37.3					40.9	2905 39.9	4680 48.3	6610 57.6
Female	DHA+ARA	9703-0001	Weight (g) Age (weeks pca)	1145 31.3	1255 32.1	1450 33.1	1680 34.3	1955 35.3					28.9	3030 41.0	4250 48.1	5620 57.3
Female	DHA+ARA	9703-0006	Weight (g) Age (weeks pca)	1865 34.0	2200 35.0	2560 35.9	2880 37.0						49.1	3600 40.0	5600 48.1	6650 56.7
Female	DHA+ARA	9703-0007	Weight (g) Age (weeks pca)	1390 32.0	1495 33.1	1620 34.0	1860 35.0	2030 35.7	2240 36.6				27.4	2850 40.0	4190 47.9	5850 56.7
Female	DHA+ARA	9704-0002	Weight (g) Age (weeks pca)	960.0 29.0	1090 30.0	1200 30.9	1370 31.9	1570 32.9	1780 33.9	2070 34.9			26.7	3110 40.0	5150 48.0	6800 57.3
Female	DHA+ARA	9704-0003	Weight (g) Age (weeks pca)	1690 32.7	1840 33.4								30.0	4000 40.0	5400 48.0	6640 57.0
Female	DHA+ARA	9705-0003	Weight (g) Age (weeks pca)	1760 34.4	2260 35.7	2500 36.6	2920 37.7						49.8	3376 39.9	5107 48.4	6894 56.9
Female	DHA+ARA	9705-0005*	Weight (g) Age (weeks pca)	1075 31.1	1120 31.4	1185 31.7	1280 32.1	1310 32.4	1265 32.7	1350 33.0	1380 33.3		22.1	2600 40.4	4000 48.0	5050 57.0
Female	DHA+ARA	9706-0001	Weight (g) Age (weeks pca)	1290 31.7	1515 32.9	1685 33.7	2060 34.9						34.5	4100 40.1	6550 48.6	7655 56.7

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-75-

Appendix 1

Listing of Weights Included in the Statistical Analyses

Gender	Regimen	Subject	Variable	Wgt1	Wgt2	Wgt3	Wgt4	Wgt5	Wgt6	Wgt7	Wgt8	Wgt9	Growth Rate g/day	Wgt_48	Wgt_57			
Female	DHA+ARA	9706-0002	Weight (g) Age (weeks pca)	1395 31.9	1710 33.0	1884 33.9	2275 35.4						34.8	2845	4645	5550		
Female	DHA+ARA	9706-0004	Weight (g) Age (weeks pca)	1550 36.7	1705 34.6	2050 35.7							36.1	2645	4225	4935		
Female	DIA+ARA	9706-0007	Weight (g) Age (weeks pca)	1235 33.4	1490 34.6	1820 35.7	1930 36.4						34.3	2505				
Female	DIA+ARA	9706-0011	Weight (g) Age (weeks pca)	1900 34.3	2105 35.0								41.0	3630	5175	6140		
Female	DIA+ARA	9706-0015	Weight (g) Age (weeks pca)	1670 34.6	1975 35.6	2210 36.4							41.6	3005	4465	5810		
Female	DIA+ARA	9706-0017	Weight (g) Age (weeks pca)	1465 32.3	1700 33.4	1895 34.3	2170 35.3							48.4	56.7			
Female	DHA+ARA	9707-0002	Weight (g) Age (weeks pca)	1775 34.3	2240 36.0	2385 36.9	2610 37.9							33.2				
Female	DHA+ARA	9708-0002	Weight (g) Age (weeks pca)	1535 33.0	1700 34.0	1980 35.0	2200 36.0							32.5	2724	4645		
Female	DIA+ARA	9708-0005	Weight (g) Age (weeks pca)	1125 32.4	1345 33.4	1610 34.4	1980 35.4								38.1	47.6	55.4	
Female	DIA+ARA	9708-0007	Weight (g) Age (weeks pca)	1200 31.3	1440 32.3	1680 33.3	1975 34.3								40.4	3121	5855	
Female	DHA+ARA	9709-0004	Weight (g) Age (weeks pca)	1350 31.9	1560 33.3	1885 34.6	2250 35.6	2475 36.3								36.6	7875	57.4
Female	DIA+ARA	9712-0003	Weight (g) Age (weeks pca)	1283 32.0	1410 33.0	1590 34.0	1850 35.0	2010 36.0										
Female	DHA+ARA	9712-0004	Weight (g) Age (weeks pca)	1575 33.0	1780 34.0	1890 34.6	2080 35.6	2530 37.6								29.7	3220	4920
																40.3	6600	57.1

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-76-

Appendix 1

Listing of Weights Included in the Statistical Analyses

Gender	Regimen	Subject	Variable	Wgt1	Wgt2	Wgt3	Wgt4	Wgt5	Wgt6	Wgt7	Wgt8	Wgt9	Growth Rate g/day	Wgt_40	Wgt_48	Wgt_57
Female	DIA+ARA	9712-0008	Weight (g)	1590	1780	1990	2475						37.2	2960	4470	5760
			Age (weeks pca)	34.0	35.0	35.8	37.4						40.1	48.1	57.1	
Female	DIA+ARA	9746-0002	Weight (g)	1249	1429	1597	1814	2110					30.1	2680	4010	5362
			Age (weeks pca)	32.7	33.7	34.7	35.7	36.7					39.9	46.9	56.9	
Female	HN	9698-0501											3546	4880		
													40.0	48.3		
Female	HN	9698-0502											3518	5972		
													40.0	47.9		
Female	HN	9698-0503											3390	4213	5319	
													40.0	48.3	57.1	
Female	HN	9698-0504											3383	5234	6667	
													40.0	48.7	57.9	
Female	HN	9698-0505											3646	4638	5653	
													40.0	48.3	57.0	
Female	HN	9699-0601											2582	4766	5731	
													40.0	49.0	57.0	
Female	HN	9699-0602											4284	4823	5986	
													40.0	48.0	57.0	
Female	HN	9699-0603											3716	4482	5674	
													40.0	47.7	56.7	
Female	HN	9699-0604											3660	4738	6355	
													40.0	48.0	57.0	
Female	HN	9699-0605											3433	5617	7603	
													40.0	48.4	57.6	
Female	HN	9701-0501											3884	5630	6650	
													40.0	47.7	57.7	

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-77-

Appendix 1
Listing of Weights Included in the Statistical Analyses

Gender	Regimen	Subject	Variable	Wgt1	Wgt2	Wgt3	Wgt4	Wgt5	Wgt6	Wgt7	Wgt8	Wgt9	Growth Rate g/day	Wgt_40	Wgt_48	Wgt_57
Female	IIM	9701-0502											3858	5420	6700	
Female	IIM	9701-0503											40.0	48.6	57.6	
Female	IIM	9701-0504											3430	4265	5085	
Female	IIM	9702-0501											40.0	47.4	57.4	
Female	IIM	9702-0502											3317	5020	6230	
Female	IIM	9702-0503											40.0	48.1	57.1	
Female	IIM	9702-0504											3302	5540	6630	
Female	IIM	9702-0505											40.0	47.7	56.7	
Female	IIM	9702-0506											2658	5310	6800	
Female	IIM	9702-0507											40.0	47.4	57.1	
Female	IIM	9702-0508											2895	3430	4530	
Female	IIM	9703-0501											40.0	47.7	57.4	
Female	IIM	9703-0505											3401	5390	6270	
Female	IIM												40.0	48.0	57.4	
Female	IIM												3141	4210	5320	
Female	IIM												40.0	47.9	57.0	
Female	IIM												3762	6040	7600	
Female	IIM												40.0	48.9	57.7	
Female	IIM												2718	4050	4940	
Female	IIM												40.0	48.9	57.4	
Female	IIM												2927	4240	5860	
Female	IIM												40.0	47.4	57.0	
Female	IIM												4085	5260	6360	
Female	IIM												40.0	48.1	57.1	
Female	IIM												3390	5760	7670	
Female	IIM												40.0	48.3	57.3	

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Appendix 1
Listing of Weights Included in the Statistical Analyses

Gender	Regimen	Subject	Variable	Wgt1	Wgt2	Wgt3	Wgt4	Wgt5	Wgt6	Wgt7	Wgt8	Wgt9	Growth Rate g/day	Wgt_40	Wgt_48	Wgt_57
Female	HM	9703-0506											3405	6170	7490	
Female	HM	9703-0507											40.0	47.9	56.9	
Female	HM	9704-0501											3085	5090	6550	
Female	HM	9705-0501											40.0	48.0	56.3	
Female	HM	9705-0502											3194	4700	5880	
Female	HM	9706-0501											40.0	48.1	57.4	
Female	HM	9706-0502											3120	4500	5702	
Female	HM	9706-0501											40.0	48.1	57.1	
Female	HM	9707-0501											3396	5000	6645	
Female	HM	9707-0502											40.0	48.3	58.1	
Female	HM	9707-0503											3041	4315	5525	
Female	HM	9707-0505											40.0	47.7	57.6	
Female	HM	9708-0501											4653	5515	6770	
Female	HM	9708-0502											40.0	47.9	56.6	
Female	HM	9708-0503											3619	5500	7080	
Female	HM	9708-0505											40.0	48.0	57.1	
Female	HM	9708-0501											3773	5785	7675	
Female	HM	9708-0502											40.0	47.9	56.9	
Female	HM	9708-0505											3716			
Female	HM	9708-0501											40.0			
Female	HM	9708-0502											3688	5440	6890	
Female	HM	9708-0503											40.0	48.1	57.6	
Female	HM	9708-0505											3454	5192	5950	
Female	HM	9708-0501											40.0	48.1	57.4	

* Four subjects had more than 9 weights used in growth rate calculation. A complete listing appears on the last page.

-79-

Appendix 1
Listing of Weights Included in the Statistical Analyses

Gender	Regimen	Subject	Variable	Wgt1	Wgt2	Wgt3	Wgt4	Wgt5	Wgt6	Wgt7	Wgt8	Wgt9	Growth Rate g/day	Wgt_40	Wgt_48	Wgt_57
Female	HM	9708-0503											2977	5165	7040	
Female	HM	9708-0506											40.0	48.1	57.4	
Female	HM	9708-0505											3864	5660	6705	
Female	HM	9709-0501											40.0	48.4	57.4	
Female	HM	9709-0502											3831	5800	7435	
Female	HM	9709-0503											40.0	47.7	57.6	
Female	HM	9709-0504											3550			
Female	HM	9709-0506											40.0			
Female	HM												3715	5205	6100	
Female	HM												40.0	48.0	56.9	
Female	HM												3195			
Female	HM												40.0			
Female	HM												3190	4590		
Female	HM												40.0	48.3		
Female	HM												3505	4500	5910	
Female	HM												40.0	48.0	57.1	

* Four subjects had more than 9 weights used in growth rate calculation. A complete listing appears on the last page.

Medical Record Number: 00000000000000000000

Appendix 1

Listing of Weights Included in the Statistical Analyses

Gender	Regimen	SUBJECT	Variable	Wgt1	Wgt2	Wgt3	Wgt4	Wgt5	Wgt6	Wgt7	Wgt8	Wgt9	Wgt10	Wgt11	Wgt12	Wgt13	Wgt14	Wgt15	Wgt16	Wgt17	Wgt18	Growth Rate	
Male	Control	9712-0301	Weight (g)	1245	1221	1245	1291	1296	1330	1369	1402	1433	1448	1465								26.1	
			Age (weeks pca)	31.6	31.7	31.9	32.0	32.1	32.3	32.4	32.6	32.7	32.7	32.9	33.0								
Male	DIA	9707-0307	Weight (g)	1649	1675	1699	1732	1778	1811	1858	1882	1918	1994	2030	2075								39.6
			Age (weeks pca)	32.4	32.6	32.7	32.9	33.0	33.1	33.3	33.4	33.6	33.7	33.9	34.0								
Female	Control	9698-0003	Weight (g)	1020	1050	1070	1080	1080	1060	1080	1070											5.6	
			Age (weeks pca)	31.1	31.3	31.4	31.6	31.7	31.9	32.0	32.1												
Female	DIA+ARA	9705-0005	Weight (g)	1075	1120	1185	1280	1310	1310	1265	1350	1380	1440	1450	1510	1515	1565	1585	1640	1680	1670	22.1	
			Age (weeks pca)	31.1	31.4	31.7	32.1	32.4	32.7	33.0	33.3	33.4	33.7	33.9	34.0	34.1	34.3	34.4	34.6	34.7	34.9		